and must be replaced at the end of each work shift during which they are exposed to the PMN substance.

- (ii) Manufacturer's Specifications. Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the PMN substance alone and in likely combination with other chemical substances in the work area.
- (4) Respiratory Protection. Each person who is reasonably likely to be exposed by inhalation in the work area to the PMN substance in the form listed in subparagraph (a)(5) of this section, engineering control measures (e.g. enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g. workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. Where engineering, work practice, and administrative controls are not feasible or inhalation exposure is still reasonably likely, each person who is reasonably likely to be exposed is provided with and is required to wear, at a minimum, a National Institute for Occupational Safety and Health ("NIOSH")-certified respirator with an Assigned Protection Factor ("APF") of _______, from the respirators listed in subparagraph (a)(6) of this section, and the respirator is used in accordance with OSHA and NIOSH respiratory protection requirements at 29 CFR 1910.134 and 42 CFR Part 84. All respirators must be issued, used, and maintained according to an appropriate respiratory protection program under the OSHA requirements in 29 CFR 1910.134.
- (5) <u>Physical States.</u> The following physical states of airborne chemical substances are listed for subparagraphs (a)(1) and (4) of this section:
 - (i) Particulate (including solids or liquid droplets),

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Commented [DIRECTION19]: Check.

- (ii) Gas/vapor (all substances in the gas form), or
- (iii) Combination Gas/Vapor and Particulate (gas and liquid/solid physical states are present; a good example is paint spray mist, which contains both liquid droplets and vapor).
- (6) <u>Authorized Respirators.</u> The following NIOSH-certified respirators meet the minimum requirements for subparagraph (a)(4) of this section:

[Note to Program Managers: Copy the appropriate individual respirator(s) from the list in the Appendix of this document, paste them here, then delete the Appendix.]

(b) <u>De Minimis Concentrations</u>. The requirements of this section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains New Chemical Exposure Limits provisions or Release to Water provisions that, respectively, specify a NCEL concentration ("TWA") or in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on

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Commented [DIRECTION21]: For exposure-based orders (and risk-based perfluoros)

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methods for protecting against such risk, into an SDS or MSDS, as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (which includes import), processed, or used in the Company's workplace, the Company must add the new information to an SDS or MSDS before the PMN substance is reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an SDS or MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

HAZARD COMMUNICATION PROGRAM

Commented [DIRECTION23]: For risk-based orders

(a) Written Hazard Communication Program. The Company must develop and implement a written hazard communication program for the PMN substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs or MSDSs, and other forms of warning material will be satisfied. The Company must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The Company may rely on an existing hazard communication program, including an existing program established under the OSHA Hazard Communication Standard (29 CFR 1910.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this section. The written program must include the following:

- (1) A list of chemical substances known to be present in the work area which are subject to a TSCA section 5(e) consent order signed by the Company or to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E. The list must be maintained in each work area where the PMN substance is known to be present and must use the identity provided on the SDS or MSDS for the substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas. If the Company is required either by another Order issued under section 5(e) of TSCA, or by a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, to maintain a list of substances, the lists must be combined with the list under this subparagraph.
- (2) The methods the Company will use to inform employees of the hazards of non-routine tasks involving the PMN substance (e.g., cleaning of reactor vessels), and the hazards associated with the PMN substance contained in unlabeled pipes in their work area.
- (3) The methods the Company will use to inform contractors of the presence of the PMN substance in the Company's workplace and of the provisions of this Order if employees of the contractor work in the Company's workplace and are reasonably likely to be exposed to the PMN substance while in the Company's workplace.

(b) Labeling.

- (1) The Company must ensure that each container of the substance in the workplace is labeled in accordance with this subparagraph (b)(1).
 - (i) The label must, at a minimum, contain the following information:
- (A) A statement of the health hazards(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section or by the Company, for the PMN substance.

- (B) The identity by which the PMN substance may be commonly recognized.
- (C) A statement of the environmental hazard(s) and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

Commented [DIRECTION24]: Check cross-reference

(D) A statement of exposure and precautionary measure(s), if any, identified either in paragraph (f) of this section, or by the Company, for the PMN substance.

Commented [DIRECTION25]: Check cross-reference

- (ii) The Company may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by subparagraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.
- (iii) The Company need not label portable containers into which the PMN substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.
- (iv) The Company must not remove or deface an existing label on containers of the PMN substance obtained from persons outside the Company unless the container is immediately re-labeled with the information specified in subparagraph (b)(1)(i) of this section.
- (2) The Company must ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this subparagraph (b)(2).
 - (i) The label must, at a minimum, contain the following information:
 - (A) The information prescribed in subparagraph (b)(1)(i) of this section.

- (B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.
- (ii) The label must not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.
 - (3) The label, or alternative forms of warning, must be legible and prominently displayed.
- (4) The label, or alternative forms of warning, must be printed in English; however, the information may be repeated in other languages.
- (5) If the label or alternative form of warning is to be applied to a mixture containing the PMN substance in combination with any other substance that is either subject to another TSCA section 5(e) Order applicable to the Company, or subject to a TSCA section 5(a)(2) SNUR at 40 CFR Part 721, subpart E, or defined as a "hazardous chemical" under the OSHA Hazard Communication Standard (29 CFR 1900.1200), the Company may prescribe on the label, SDS or MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the Company determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under this Order, the Company must seek a determination of equivalency for such alternative control measures pursuant to 40 CFR 721.30 before prescribing them under this subparagraph (b)(5).
- (6) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be added to the label within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include

import), processed, or used in the Company's workplace, the Company must add the new information to the label before the PMN substance is reintroduced into the workplace.

(c) Safety Data Sheets or Material Safety Data Sheets.

- (1) The Company must obtain or develop an SDS or MSDS for the PMN substance.
- (2) The SDS or MSDS must contain, at a minimum, the following information:
- (i) The identity used on the container label of the PMN substance under this section, and, if not claimed confidential, the chemical and common name of the PMN substance. If the chemical and common names are claimed confidential, a generic chemical name must be used.
- (ii) Physical and chemical characteristics of the substance known to the Company, (e.g., vapor pressure, flash point).
- (iii) The physical hazards of the substance known to the Company, including the potential for fire, explosion, and reactivity.
- (iv) The potential human and environmental hazards as specified in paragraph (f) of this section.

Commented [DIRECTION26]: Check

- (v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the PMN substance known to the Company.
 - (vi) The primary routes of exposure to the PMN substance.
- (vii) Precautionary measures to control worker exposure and/or environmental release required by this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide substantially the same degree of protection as the identified control measures.

 The SDS or MSDS must identify any New Chemical Exposure Limits specified in paragraph (b) of

the New Chemical Exposure Limit section of this Order and must contain the information specified in the graduated respirator table in paragraph (e)(2) of the New Chemical Exposure Limit section.

Commented [DIRECTION27]: Delete if there is no NCEL

- (viii) Any generally applicable precautions for safe handling and use of the PMN substance which are known to the Company, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.
- (ix) Any generally applicable control measures which are known to the Company, such as appropriate engineering controls, work practices, or personal protective equipment.
 - (x) Emergency first aid procedures known to the Company.
 - (xi) The date of preparation of the SDS or MSDS or of its last revision.
- (xii) The name, address, and telephone number of the Company or another responsible party who can provide additional information on the chemical substance and any appropriate emergency procedures.
- (3) If no relevant information is found or known for any given category on the SDS or MSDS, the Company must mark the SDS or MSDS to indicate that no applicable information was found.
- (4) Where multiple mixtures containing the PMN substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the Company may prepare one SDS or MSDS to apply to all of these multiple mixtures.
- (5) If the Company becomes aware of any significant new information regarding the hazards of the PMN substance or ways to protect against the hazards, this new information must be

added to the SDS or MSDS within 3 months from the time the Company becomes aware of the new information. If the PMN substance is not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to the SDS or MSDS before the PMN substance is reintroduced into the workplace.

- (6) The Company must ensure that persons receiving the PMN substance from the Company are provided an appropriate SDS or MSDS with their initial shipment and with the first shipment after an SDS or MSDS is revised. The Company may either provide the SDS or MSDS with the shipped containers or send it to the person prior to or at the time of shipment.
- (7) The Company must maintain a copy of the SDS or MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.
- (8) The SDS or MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for the PMN substance and must be readily accessible during each work shift to employees when they are in their work areas.
- (9) The SDS or MSDS must be printed in English; however, the information may be repeated in other languages.
- (d) <u>Employee Information and Training</u>. The Company must ensure that employees are provided with information and training on the PMN substance. This information and training must be provided at the time of each employee's initial assignment to a work area containing the PMN

substance and whenever the PMN substance is introduced into the employee's work area for the first time.

- (1) The information provided to employees under this paragraph must include:
 - (i) The requirements of this section.
 - (ii) Any operations in the work area where the PMN substance is present.
- (iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances required by subparagraph (a)(1) of this section and SDSs or MSDSs required by paragraph (c) of this section.
 - (2) The training provided to employees must include:
- (i) Methods and observations that may be used to detect the presence or release of the PMN substance in or from an employee's work area (such as exposure monitoring conducted by the Company, continuous monitoring devices, visual appearance, or odor of the substance when being released).
- (ii) The potential human health and environmental hazards of the PMN substance as specified in paragraph (f) of this section.
- (iii) The measures employees can take to protect themselves and the environment from the PMN substance, including specific procedures the Company has implemented to protect employees and the environment from exposure to the PMN substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under this Order, or alternative control measures which EPA has determined under 40 CFR 721.30 provide the same degree of protection as the specified control measures.

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- (iv) The requirements of the hazard communication program developed by the Company under this section, including an explanation of the labeling system and the SDS or MSDS required by this section and guidance on obtaining and using appropriate hazard information.
- (e) <u>De Minimis Concentrations</u>. The requirements of this Hazard Communication section do not apply to quantities of the PMN substance that are (1) present in the work area only as a mixture and (2) at a concentration not to exceed 1.0 percent by weight or volume (0.1 percent by weight or volume if the PMN substance is identified as a potential carcinogen in paragraph (f) of the Hazard Communication Program section of this Order). This exemption is not available if the Company has reason to believe that, during intended activities, the PMN substance in the mixture may be reconcentrated above the 1.0 or 0.1 percent level, whichever applies. If this Order contains (1) New Chemical Exposure Limits provisions that specify a NCEL concentration less than the de minimis concentration specified here, or (2) Release to Water provisions that prohibit release to water or specify in-stream concentration ("N") less than the de minimis concentration specified here, then this de minimis exemption does not apply to those provisions.
- (f) Human Health, Environmental Hazard, Exposure, and Precautionary Statements. The following human health and environmental hazard and precautionary statements must appear on each label as specified in paragraph (b) and the SDS or MSDS as specified in paragraph (c) of this section:
 - (1) Human health hazard statements. This substance may cause:
 - (i) skin irritation.

(ii) respiratory complications.

	(iii) central nervous system effects.	
(iv) internal organ effects.		
(v) birth defects.		
	(vi) reproductive effects.	
	(vii) cancer.	
	(viii) immune system effects.	
	(ix) developmental effects.	
(2) Human hazard precautionary statements. When using this substance:		
	(i) avoid skin contact.	
	(ii) avoid breathing the substance.	
	(iii) avoid ingestion.	
	(iv) use respiratory protection, or maintain workplace airborne concentrations at or	
below an 8-ho	ur time-weighted average of [Note to Program Managers: Add STEL if	
applicable.]		
	(v) use skin protection.	
(3) En	vironmental hazard statements. This substance may be:	
	(i) toxic to fish.	
	(ii) toxic to aquatic organisms.	
(4) En	vironmental hazard precautionary statements. Notice to users:	
	(i) disposal restrictions apply.	
	(ii) spill clean-up restrictions apply.	
	(iii) do not release to water.	

(5) The human and environmental hazard and precautionary statement on the label prepared pursuant to paragraph (b) of this section must be followed by the statement: "See the SDS or MSDS for details."

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(6) The Company may use alternative labeling that meets the criteria of the Globally Harmonized System (GHS) and OSHA Hazard Communication Standard for Acute Inhalation Standard Category 1, including Symbol, Signal Word, and Hazard Statement.

(g) Existing Hazard Communication Program. The Company need not take additional actions if existing programs and procedures satisfy the requirements of this section.

MANUFACTURING

- (a)(1) <u>Prohibition</u>. The Company must not cause, encourage, or suggest the manufacture (which includes import) of the PMN substance by any other person.
- (2) <u>Sunset Following SNUR</u>. Subparagraph (a)(1) will expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.
- (3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company must notify each person whom it causes, encourages or suggests to manufacture the PMN substance of the existence of the SNUR.

Commented [DIRECTION29]: Include in all orders with this section

Commented [DIRECTION30]: Only paragraph (a) is included in exposure based orders.

(b)	The Company must not manufacture the PMN substance:
	(1) In non-enclosed processes;
	(2) In the United States;
	(3) Beyond an aggregate manufacture (which includes import) volume of
	(4) Beyond an annual manufacture (which includes import) volume of
	(5) In the form of a powder;
	(6) In the form of a solid;
	(7) In the form of a liquid;
	(8) In the form of a gas; or
	(9) Other: .

MANUFACTURING

(a)(1) <u>Prohibition.</u> The Company must not cause, encourage, or suggest the manufacture (which includes import) of the PMN substance by any other person.

- (2) <u>Sunset Following SNUR.</u> Subparagraph (a)(1) will expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.
- (3) <u>Notice of SNUR</u>. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company must notify

Commented [DIRECTION31]: Use this alternate Manufacturing Section for orders with Contract Manufacturers. Delete previous Manufacturing Section in it's entirety.

each person whom it causes, encourages or suggests to manufacture the PMN substance of the existence of the SNUR.

- (4) Subparagraph (a)(2) does not negate the effects of any fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2).
- (b) <u>Contract Manufacturer</u>. Not withstanding paragraph (a), the Company may cause the Contract Manufacturer(s) identified in the PMN and listed in the Preamble of this Order to manufacture (which includes import) the PMN substance according to the following conditions (the Company may petition EPA pursuant to Section VI of this Order to include additional Contract Manufacturers):
- (1) The Contact Manufacturer must be under contract to the Company to manufacture the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.
- (2) The Company must obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for the Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture.
- (3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company must immediately cease to cause the Contract Manufacturer to manufacture the PMN substance,

unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

- (i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with the conditions specified in the Consent Order for Contract Manufacturer.
- (ii) That, within 15 working days of notifying the Contract Manufacturer of the noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.
- (iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (B) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company must immediately cease to cause the Contract Manufacturer to manufacture the PMN substance, must notify EPA of the failure to comply, and is permitted to resume causing the Contract Manufacturer to manufacture the PMN substance only upon written notification from the Agency.
- (c) The Company must not manufacture the PMN substance:
 - (1) In non-enclosed processes;
 - (2) In the United States;
 - (3) Beyond an aggregate manufacture (which includes import) volume of
 - (4) Beyond an annual manufacture (which includes import) volume of ______;
 - (5) In the form of a powder;

(6) In the form of a solid;	
(7) In the form of a liquid;	
(8) In the form of a gas; or	
(9) Other:	
PROCESSING	Commented [DIRECTION32]: Exposure based orders (HH eco) don't include this section.
(a) The Company must not process the PMN substance:	-
(1) In non-enclosed processes;	
(2) Beyond the site of manufacture (which includes import);	
(3) In the form of a powder;	
(4) In the form of a solid;	
(5) In the form of a liquid;	
(6) In the form of a gas; or	
(7) Other:	
USE	Commented [DIRECTION33]: Exposure based orders (HH eco) don't include this section.
(a) The Company must not use the PMN substance:	
(1) In non-enclosed processes;	
(2) Beyond the site of manufacture (which includes import);	
(3) Other than as an intermediate;	
(4) Other than as a site-limited intermediate;	
(5) As an intermediate where the concentration of the PMN substance in the product	
intended for distribution in commerce exceedspercent;	

(6) Other than as described in the PMN;
(7) For non-industrial applications;
(8) For commercial applications;
(9) For non-commercial applications;
(10) In consumer products;
(11) In the form of a powder;
(12) In the form of a solid;
(13) In the form of a liquid;
(14) In the form of a gas;
(15) Involving an application method that generates a vapor, mist, or aerosol;
(16) Involving an application method that generates a dust; or
(17) Other:

DISTRIBUTION

Commented [DIRECTION34]: Include paragraph (a) in all orders unless there is a good reason not to.

- (a) Export Notice Requirement. No later than the date of distribution, the Company must notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.
- (b) <u>Distribution Requirements.</u> Except after the PMN has been completely reacted (or ______),

Commented [DIRECTION35]: Always include paragraph (b) in risk-based orders, unless there is a good reason not to

- or [Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., "incorporated into a polymer matrix", "adhered onto film", or similar. If there is no such state, or if the substance cannot be completely reacted/cured, delete the blue text above.] as provided in paragraph (c), the Company is permitted to distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:
- (1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice must contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.
- (2) Not further distribute the PMN substance to any other person, other than for disposal, until after the PMN substance has been completely reacted (cured) or ______. [Note to Program Managers: If applicable to the specific PMN substance, identify a state or states in which exposure to the PMN substance no longer presents a significant risk, e.g., "incorporated into a polymer matrix", "adhered onto film", or similar.]
- (3) Comply with the same requirements and restrictions, if any, required of the Company in the Protection in the Workplace section, or, as an alternative to the respirator requirements in the Protection in the Workplace Section, the New Chemical Exposure Limit sections of this Order, or

Commented [DIRECTION36]: If there is no such state or curing for the substance, delete this portion.

For orders with CONTRACT MANUFACTURERS, insert the following:

A Contract Manufacturer identified in a fully executed Consent Order for Contract Manufacturer entered into under paragraph (b)(2) of the Manufacturing section of this Order may further distribute the PMN substance(s) to the Company.

Commented [DIRECTION37]: Edit (b)(3)-(7) to omit restrictions that are not included in your order.

⁽⁴⁾ Comply with the same requirements and restrictions, if any, required of the Company

in the Hazard Communication Program section of this Order, or		
(5) Comply with the same environmental release restrictions, if any, required of the		
Company in the Disposal and Release to Water sections of this Order, or		
(6) Not process the PMN substance:		
(i) In non-enclosed processes;		
(ii) At a site not in that person's control;		
(iii) Except as described in the PMN;		
(iv) In the form of a powder;		
(v) In the form of a solid;		
(vi) In the form of a liquid;		
(vii) In the form of a gas; or		
(viii) Other:		
(7) Not use the PMN substance:		
(i) At a site not under the person's control;		
(ii) In non-enclosed processes;		
(iii) Other than as an intermediate;		
(iv) Other than as a site-limited intermediate; or		
(v) As an intermediate where the concentration of the PMN substance in the		
product intended for distribution in commerce exceedspercent;		
(vi) Other than as described in the PMN;		
(vii) For non-industrial applications;		
(viii) For commercial use;		
(ix) For non-commercial use;		

(x) In consumer products;		
(xi) In the form of a powder;		
(xii) In the form of a solid;		
(xiii) In the form of a liquid;		
(xiv) In the form of a gas;		
(xv) Involving an application method that generates a vapor, mist, or aerosol;		
(xvi) Involving an application method that generates a dust; or		
(xvii) Other:		

- (c) <u>Temporary Transport and Storage</u>. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:
- (1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).
- (2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).
- (3) The sealed containers must be labeled in accordance with paragraph (b)(2) of the Hazard Communication Program section of this Order.
- (d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the

Commented [DIRECTION38]: If there is no Haz Com section, replace item (3) with the following (adapted from the Haz Com section):

The Company shall ensure that each of the sealed containers of the substance leaving its workplace for distribution in commerce is labeled with the following information:

A statement of the health hazards(s) and precautionary measure(s), if any, identified by the Company for the PMN substance; the identity by which the PMN substance may be commonly recognized; a statement of the environmental hazard(s) and precautionary measure(s), if any, identified by the Company for the PMN substance; a statement of exposure and precautionary measure(s), if any, identified by the Company for the PMN substance; and the name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures. The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after paragraph (b) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company must cease supplying the substance to that recipient, unless the Company is able to document each of the following:

- (1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.
- (2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage in a significant new use without submitting a significant new use notice to EPA.
- (3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company must cease supplying the PMN substance to that recipient, must notify EPA of the failure to comply, and is permitted to resume supplying the PMN substance to that recipient only upon written notification from the Agency.

- (e) Sunset Following SNUR and Notification of SNUR. (1) Paragraphs (b) and (c) of this Distribution section will expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, paragraphs (b) and (c) of this Distribution section will not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.
- (2) When EPA promulgates a final SNUR for the PMN substance and paragraph (b) of this Distribution section expires in accordance with subparagraph (e)(1), the Company must notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would require significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the <u>Federal Register</u> or the Code of Federal Regulations.

DISPOSAL

The Company must dispose of the PMN substance and any waste stream containing the PMN substance only as follows. This provision does not supersede or preempt any applicable federal, state, and local laws and regulations if those laws are more stringent than the requirements below.

- (1) The PMN substance must be disposed of only by:
 - (i) incineration;
 - (ii) landfill;
 - (iii) deep well injection;

Commented [DIRECTION39]: Exposure based orders (HH or eco) don't include this section. Include Disposal and/or Release to Water sections in all risk-based orders with ecotox concerns or HH concerns from drinking water exposure.

Choose the applicable restrictions from the numbered list. If there is more than one, label them with lowercase letters. "(a)" If they have subordinate list, label that list with numbers. "(1)"

(iv) other:
(2) Waste streams from manufacture must be disposed of only by:
(i) incineration;
(ii) landfill;
(iii) deep well injection;
(iv) other:
(3) Waste streams from processing must be disposed of only by:
(i) incineration;
(ii) landfill;
(iii) deep well injection;
(iv) other:
(4) Waste streams from use must be disposed of only by:
(i) incineration;
(ii) landfill;
(iii) deep well injection;
(iv) other:
(5) The Company must not dispose of or release the PMN substance into the environment

RELEASE TO WATER

(a) This provision does not supersede or preempt any applicable federal, state, and local laws and regulations. (Those other laws may be more stringent than the requirements below.) TheCompany is prohibited from any predictable or purposeful release of the PMN substance, or any

Commented [DIRECTION40]: Exposure based orders (HH or eco) don't include this section. Include Disposal and/or Release to Water sections in all risk-based orders with ecotox concerns or HH concerns from drinking water exposure.

Chose the applicable restrictions from the numbered list. If there is more than one, label them with lowercase letters. "(a)" If they have subordinate list, label that list with numbers. "(1)"

waste stream from	(manufacturing/processing/use) containing the PMN		
substance:			
(1) Into the waters of t	he United States;		
(2) Into the waters of t	he United States without application of one or more of the following		
specified treatment technologie	es either by the discharger or, in the case of a release through		
publicly-owned treatment wor	ks, by a combination of treatment by the discharger and the publicly-		
owned treatment works:			
(a) Chemical p	recipitation and settling;		
(b) Biological	treatment (activated sludge or equivalent) plus clarification;		
(c) Stream strip	oping;		
(d) Resin or ac	tivated carbon adsorption;		
(e) Chemical d	estruction or conversion;		
(f) Primary wa	stewater treatment;		
(3) Into the waters of the United States without primary wastewater treatment, and			
secondary wastewater treatmen	nt as defined in 40 CFR Part 133.		
(4)(a) Into the waters of	of the United States if the quotient from the formula:		
	of kilograms/day/site released		
exceeds, when calcul	ated using the methods described in 40 CFR 721.91. However, 40		
CFR 721.91(a)(4) does not app	bly. Instead, if the waste stream containing the PMN substance will		
be treated using,	then the amount of PMN substance reasonably likely to be removed		
from the waste stream by such	treatment may be subtracted in calculating the number of kilograms		

released. No more than ___percent removal efficiency may be attributed to such treatment. [Note to Program Managers: Use this language, starting from "However, 40 CFR 721.91(a)(4) does not..." only when EPA has received and reviewed removal rate data..]

(b) In lieu of calculating the quotient in subparagraph (4)(a), monitoring or alternative calculations may be used to predict the surface water concentration expected to result from the intended release of the substance, if the monitoring procedures or calculations have been approved for such purpose by EPA. EPA will review and act on a written request to approve monitoring procedures or alternative calculations within 90 days after such a request is received. The Agency will inform the Company of the disposition of such requests in writing and, where a request is denied, will explain the reasons therefore.

III. RECORDKEEPING

Commented [DIRECTION41]: Delete the recordkeeping requirements for sections that aren't in your order.

- (a) <u>Records.</u> The Company must maintain the following records until 5 years after the date they are created and must make them available for inspection and copying by EPA in accordance with section 11 of TSCA:
- (1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA

sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company must keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

- (2) Records documenting the manufacture (which includes import) volume of the PMN substance and the corresponding dates of manufacture;
- (3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (which includes import) to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;
- (4) Records documenting the address of all sites of manufacture (which includes import), processing, and use;
- (5) Records documenting establishment and implementation of a program for the use of any applicable personal protective equipment required pursuant to the Protection in the Workplace section of this Order;
- (6) Records documenting the determinations required by the Protection in the Workplace section of this Order that chemical protective clothing is impervious to the PMN substance;
- (7) Records required by paragraph (f). of the New Chemical Exposure Limits section of this Order, if applicable;

- (8) Records documenting establishment and implementation of the hazard communication program required by the Hazard Communication Program section of this Order;
- (9) Copies of labels required under the Hazard Communication Program section of this Order;
- (10) Copies of Material Safety Data Sheets required by the Hazard Communication Program section of this Order;
- (11) Records documenting compliance with any applicable manufacturing, processing, use, and distribution restrictions in the Manufacturing, Processing, Use, and Distribution sections of this Order, including distributees' written agreement to comply with the Distribution section of this Order;
- (12) Records documenting compliance with any applicable disposal requirements under the Disposal section of this Order, including method of disposal, location of disposal sites, dates of disposal, and volume of PMN substance disposed. Where the estimated disposal volume is not known to the Company and is not reasonably ascertainable by the Company, the Company must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements;
- (13) Records documenting establishment and implementation of procedures that ensure compliance with any applicable water discharge limitation in the Release to Water section of this Order;
- (14) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,
- (15) The Company must keep a copy of this Order at each of its sites where the PMN substance is manufactured (which includes import).

Commented [DIRECTION42]: Edit as appropriate for your order.

- (b) <u>Applicability</u>. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.
- (c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid OMB Control Number 2070-0012.

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

- (a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:
- Expected dates and times when the PMN substance will be in production within the subsequent 12 months;
- (2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

- (3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;
- (4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;
 - (5) Records required by the Recordkeeping section of this Order; and/or,
- (6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.
- (b) <u>Company's Response</u>. The Company must respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response must be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response must demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.
- (c) <u>Confidential Business Information</u>. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) will be protected in accordance with §14 of TSCA and 40 CFR part 2. In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Company must certify that it is true and accurate that the Company has:
 - (1) Taken reasonable measures to protect the confidentiality of the information;
- (2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

- (3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Company; and
- (4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) <u>Scope.</u> This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) <u>Before NOC.</u> If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture or import ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1)(B) of TSCA and 40 CFR part 720 before commencing manufacture (which includes import) of the PMN substance.

- (2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest must comply with the terms of this Order and will not be required to submit a new PMN to EPA.
- (c) <u>Definitions</u>. The following definitions apply to this Successor Liability section of the Order:
- (1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).
- (2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company must provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order. (2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company must, by registered mail, submit the fully executed Notice of Transfer document to EPA at:

Postal Mail Address

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1200 Pennsylvania Avenue, N.W.

Washington, D.C. 20460

Alternatively, the document may be submitted by courier:

U.S. Environmental Protection Agency

New Chemicals Management Branch (7405M)

1201 Constitution Avenue, N.W.

Washington, D.C. 20004

(3) <u>Transfer Document.</u> Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured. Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

- (1) The Company will be liable for compliance with the requirements of this Order until the effective date of the transfer described above.
- (2) The Successor in Interest will be liable for compliance with the requirements of this Order effective as of the date of transfer.
- (3) Nothing in this section may be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.
- (f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured by the Company up to the date of transfer will count towards the test trigger applicable to the Successor in Interest.

Commented [DIRECTION43]: Delete if order has no triggered testing.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order, including, but not limited to, testing requirements, workplace protections, disposal requirements, or discharge limits. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke the substantive

provisions of this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein are no longer necessary to protect against an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

<u>Waiver.</u> By consenting to the entry of this Order, the Company waives its rights to receive service of this Order no later than 45 days before the end of the applicable review period pursuant to section 5(e)(1)(B) of TSCA and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

Date	Maria J. Doa, Ph.D., Director
	Chemical Control Division
	Office of Pollution Prevention and Toxics
Date	Name:
	Title:
	Company:

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture (which includes import) the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"SDS" means safety data sheet, the written listing of data for the chemical substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT SECTION 5(e) CONSENT ORDER

Company (Transferor)	MN Number
and liabilities associated with manufacture of	
of transfer, all actions or omissions governed manufacture, processing, use, distribution in o	commerce and disposal of the PMN substance, will est. Successor in Interest also certifies that it is
3. Confidential Business Information. The S	uccessor in Interest hereby:
reasserts,	
relinquishes, or	
modifies	
14 of TSCA and 40 CFR part 2, for the PMN indicated, that designation will be deemed to indicated, such modification will be explained Information which has been previously disclo	claims made by the Company, pursuant to Section substance(s). Where "reasserts" or "relinquishes" is apply to all such claims. Where "modifies" is I in detail in an attachment to this Notice of Transfer. sed to the public (e.g., a chemical identity that was would not subsequently be eligible for confidential

In order to make a confidentiality claim for information submitted to EPA, an authorized official of the Successor in Interest must certify that it is true and accurate that the Successor in Interest has:

- (1) Taken reasonable measures to protect the confidentiality of the information;
- (2) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- (3) A reasonable basis to conclude that the disclosure of the information is likely to cause substantial harm to the competitive position of the Successor in Interest; and
- (4) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

CBI claims for chemical identity must be accompanied by a generic chemical identity, which may be that used for the PMN.

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT SECTION 5(e) CONSENT ORDER

(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

NOTICE OF TRANSFER OF TOXIC SUBSTANCES CONTROL ACT SECTION 5(e) CONSENT ORDER (continued)

Successor's Technical Contact	
Address	
City, State, Zip Code	
Phone	

APPENDIX

LIST OF RESPIRATORS

Note to Program Managers: Copy the table with respirators in the appropriate APF category below, then paste that table into the Protection in the Workplace section (a)(6) of the Consent Order (found in the boilerplate on page 12). For example, if the exposure to the PMN substance is expected to be in particulate form, copy the Particulate/Aerosol Respirator table for the APF you need below.

Do not copy the red bold headings (e.g., Particulate/Aerosol Respirator - APF of 10) into the body of the Order. Adjust numbering for respirators as necessary in the table inserted into the Order. None of the tables require any editing unless specified.

After you have inserted the relevant table into the Consent Order, delete this Appendix.

Particulate/Aerosol Respirator - APF of 10

Assigned Protection Factor (APF)	Type of Respirator
10	(I) Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator]
	(II) Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. [Note: for filtering facepieces, an APF of 10 can only be achieved if the respirator is qualitatively or quantitatively fit tested on individual workers]. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator]
	(III) Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(IV) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator]
	(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical,

Assigned Protection Factor (APF)	Type of Respirator
	delete this respirator]

^{*}A full facepiece air-purifying respirator, although it has a higher APF of 50, is required to provide full face protection because the PMN substance presents significant exposure concern for mucous membranes, eyes, or skin.

Particulate/Aerosol Respirator - APF of 25

Assigned Protection Factor (APF)	Type of Respirator
25	(I) Any NIOSH-certified powered air-purifying respirator equipped with a
	hood or helmet and HEPA filters.
	(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters.
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.

Particulate/Aerosol Respirator - APF of 50

Assigned Protection Factor (APF)	Type of Respirator
50	(I) Any NIOSH-certified air-purifying full facepiece respirator equipped
	with N100 (if oil aerosols absent), R-100, or P-100 filter(s).
	(II) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and equipped with HEPA filters. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(III) Any NIOSH-certified pressure-demand or other positive pressure mode
	supplied-air respirator equipped with a half-mask. [Note to Program

Assigned Protection Factor (APF)	Type of Respirator
	Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].
	(IV) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
	(V) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

Particulate/Aerosol Respirator - APF of 1000

Assigned Protection Factor (APF)	Type of Respirator
1,000	 (I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters. (II) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet* and N100 (if oil aerosols absent), R100, or P100 filters with evidence demonstrating protection level of 1,000 or greater.* [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. (IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater.* [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(V) Any NIOSH-certified pressure-demand supplied-air respirator equipped with a full facepiece.

* OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Assigned Protection Factor (APF)	Type of Respirator
10	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
	(I) Any NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].
	(II) Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.
	(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece). [Note to Program Manager: If a

Assigned Protection Factor (APF)	Type of Respirator
	concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	racepiece respirator].
	(III) Any NIOSH-certified negative pressure (demand) self-contained
	breathing apparatus (SCBA) equipped with a half-mask. [Note to Program
	Manager: If a concern exists for eye/skin exposure from the chemical,
	delete this respirator].

Assigned Protection Factor (APF)	Type of Respirator
25	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
	(I) Any NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.
	(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges.
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

Assigned Protection Factor (APF)	Type of Respirator
50	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
	(I) Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific).
	(II) Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific).
	(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(V) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood, helmet, or a full facepiece.
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
	(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical,

Assigned Protection Factor (APF)	Type of Respirator
	delete the half facepiece respirator].
supplied-air respirator equipped with a tight-fitting facepiece (half or	(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(IV) Any NIOSH-certified negative pressure (demand) self-contained
	breathing apparatus (SCBA) equipped with a hood, helmet, or a full
	facepiece.

Assigned Protection Factor (APF)	Type of Respirator
1,000	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA: (I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance
	specific) cartridges. (II) Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges with evidence demonstrating protection level of 1,000 or greater. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(VI) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

Assigned Protection Factor (APF)	Type of Respirator
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.
	(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]
	(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.

^{*} OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Assigned Protection Factor (APF)	Type of Respirator
10	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
	(I) Any NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters. [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator]. (II) Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.

Assigned Protection Factor (APF)	Type of Respirator
	(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(V) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the this respirator].
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece). [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].
	(III) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete this respirator].

Assigned Protection		
Factor (APF)	Type of Respirator	
25	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:	
	(I) Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid	

Assigned Protection Factor (APF)	Type of Respirator
	gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.
	(II) Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters.
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece.
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet.
	(II) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.

Assigned Protection Factor (APF)	Type of Respirator
50	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
	(I) Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters.
	(II) Any NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half or full facepiece) equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. [[Note to Program Manager: If a concern exists for eye/skin

Assigned Protection Factor	Type of Respirator
(APF)	exposure from the chemical, delete the half facepiece respirator].]
	(III) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].]
	(V) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].]
	(VI) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.
	If No Cartridge Service Life Testing has been Conducted:
	(I) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece.
	(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].]
	(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [[Note to Program Manager: If a concern exists for eye/skin exposure from the chemical, delete the half facepiece respirator].]
	(IV) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece.

Assigned Protection Factor	Type of Respirator	
(APF) 1000	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:	
	(I) Any NIOSH-certified powered air purifying full facepiece respirator equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters.	
	(II) Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters with evidence demonstrating protection level of 1,000 or greater. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]	
	(III) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece.	
	(IV) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. * [Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]	
	(V) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece.	
	If No Cartridge Service Life Testing has been Conducted:	
	(I) Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].	
	(II) Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. *[Note to Program Manager: Copy and paste the * and the footnote below the table when selecting this respirator.]	
	(III) Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].	

^{*} OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have

evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-14-0314

Number: P-14-0314

TSCA Section 5(a)(3) Determination: Chemical substance not likely to present an

unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic: Poly aliphatic phosphate.

Assessed Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended use(s) (generic): Industrial flame retardant.

Known and reasonably foreseen use(s): No other uses were identified.

Summary: The chemical substance is not likely to present an unreasonable risk based on low human health concern and low environmental concern. Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health concern, and low environmental concern.

Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk. EPA estimated a number of physical-chemical and fate properties of this new chemical substance using received data for the new chemical substance. Overall, these estimates were indicative of low potential for this chemical substance to volatilize into the air and a moderate potential for this chemical to migrate into ground water. Removal of the substance in wastewater treatment is unlikely due to low biodegradability, low sorption, and low stripping.

Persistence²: Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. EPA estimated biodegradation half-lives of this new chemical substance using received data for the new chemical substance. These data indicate that the chemical substance is persistent.

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¹ Intended uses are those identified in the section 5(a) notification. EPA identifies "known" and "reasonably foreseen" uses of the new chemical substance based on evidence of current use of the new chemical substance outside the United States and evidence of the current uses of chemical substances that are structurally analogous to the new chemical substance. EPA identifies uses based on searches of internal CBI EPA PMN databases (containing use information on analog chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REA CH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

² Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

Bioaccumulation³: Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. EPA estimated the potential for the new chemical substance to bioaccumulate using received data for the new chemical substance. These data indicate that this chemical substance has low bioaccumulation potential.

Human Health Hazard⁴: Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated a low to moderate concern for the human health hazard of this chemical substance based on submitted data on the PMN substance, estimated physical/chemical properties (which indicate that absorption of the low molecular weight fraction is moderate all routes), and estimates of potential hazard based on analogous chemical substances/structure-activity relationships, but concludes that since the potential for exposure is low, there is low concern.

Environmental Hazard⁵: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

³ Bioaccumulation. A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

⁴ A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories ^{6,7}, structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

⁵ A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values

A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is higher than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L, or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures-p2-framework-manual).

⁶ TSCA New Chemicals Program (NCP) Chemical Categories (https://www.epa.gov/sites/production/files/2014-10/documents/ncp-chemical-categories-august-2010-version-0.pdf)

⁷Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. (http://www.oecd.org/officialdocuments/publicdisply documentpdf?cote=env/jm/mono(2014)4&doclanguage=en)

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-14-0314

upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA received three acute ecotoxicity studies for this new chemical substance. Based on the submitted data, EPA concludes that this chemical substance has low to moderate environmental hazard, but due to no predicted water releases, there is low concern for environmental risks.

Potential Exposures: The exposure to a new chemical substance is potentially relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. Based on exposure simulation studies on the PMN substance and on an analogous chemical substance, EPA estimated potential dermal exposures in the workplace and to consumers from use of the chemical substance in products containing flame retardants. These estimates indicate that the chemical substance has low potential for exposure to humans. Therefore, EPA has determined that the chemical substance is not likely to present an unreasonable risk for the intended use.

Potentially Exposed or Susceptible Subpopulation(s): Workers and consumers are not expected to be exposed to the PMN substance at levels that would present an unreasonable risk. The risk assessment was based upon toxicity data and exposure simulation studies on the PMN substance and on close structural analogs.

7/31/17	/s/
Date:	Chief, New Chemicals Management Branch,
	Chemical Control Division,
	Office of Pollution Prevention and Toxics

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

Number: P-18-0044 & P-18-0045

TSCA Section 5(a)(3) Determination: The chemical substances are not likely to present an

unreasonable risk (5(a)(3)(C))

Chemical Name:

Generic (P-18-0044): Fatty acids

Generic (P-18-0045): Fatty acids, alkyl esters

Assessed Conditions of Use (intended, known, or reasonably foreseen)¹:

Intended use(s) (generic) (P-18-0044): Intermediate species

Intended use(s) (generic) (P-18-0045): Application coating

Known and reasonably foreseen use(s) (P-18-0044): Chemical intermediate; Lubricant and lubricant additive; Viscosity adjustor; Coating.

Known and reasonably foreseen use(s) (P-18-0045): Lubricant intermediate; Mold release agent; Plasticizer; Processing aid.

Summary: These chemical substances are not likely to present an unreasonable risk based on low/moderate human health hazard and low environmental hazard. Although EPA estimated that the new chemical substances would be persistent, this did not indicate a likelihood that the chemical substances would present an unreasonable risk, given that the chemical substances have low potential for bioaccumulation, low-moderate human health hazard, and low environmental hazard.

Fate: Environmental fate is the determination of which environmental compartment(s) a chemical moves to, the expected residence time in the environmental compartment(s) and removal and degradation processes. Environmental fate is an important factor in determining exposure and thus in determining whether a chemical may present an unreasonable risk. EPA estimated a number of physical-chemical and fate properties of these new chemical substances using data for analogous chemicals and EPI (Estimation Programs Interface) Suite, a suite of physical/chemical property and environmental fate estimation programs (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface). Overall, these estimates are indicative of low potential for these chemical substances to volatilize into the air and a low potential to migrate into ground water. Removal of the substances in wastewater treatment is likely due to sorption and biodegradation.

Persistence²: Persistence is relevant to whether a new chemical substance is likely to present an unreasonable risk because chemicals that are not degraded in the environment at rates that

¹ Intended uses are those identified in the section 5(a) notification. EPA identifies "known" and "reasonably foreseen" uses of the new chemical substance based on evidence of current use of the new chemical substance outside the United States and evidence of the current uses of chemical substances that are structurally analogous to the new chemical substance. EPA identifies uses based on searches of internal CBI EPA PMN databases (containing use information on analog chemicals), other U.S. government public sources, the National Library of Medicine's Hazardous Substances Data Bank (HSDB), the Chemical Abstract Service STN Platform, REACH Dossiers, technical encyclopedias (e.g., Kirk-Othmer and Ullmann), and Internet searches.

² Persistence: A chemical substance is considered to have limited persistence if it has a half-life in water, soil or sediment of less than 2 months or there are equivalent or analogous data. A chemical substance is considered to be

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

prevent substantial buildup in the environment, and thus increase potential for exposure, may present a risk if the substance presents a hazard to human health or the environment. EPA estimated biodegradation half-lives of these new chemical substances using data for analogous chemicals and EPI Suite. The anaerobic biodegradation estimates indicate that the chemical substances are persistent.

Bioaccumulation³: Bioaccumulation is relevant to whether a new chemical substance is likely to present an unreasonable risk because substances that bioaccumulate in aquatic and/or terrestrial species pose the potential for elevated exposures to humans and other organisms via food chains. The chemical substance has low bioaccumulation potential based on data for analogous chemicals and EPI Suite. These estimates indicate that these new chemical substances have low bioaccumulation potential.

Human Health Hazard⁴: Human health hazard is relevant to whether a new chemical substance is likely to present an unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated the human health hazard of these chemical substances based on their estimated physical/chemical properties, and by comparing them to structurally analogous chemical substances for which there is information on human health hazard. EPA concludes there is low-moderate concern for human health hazard for the chemical substances based on concern for serious eye damage (P-18-0044 only) and concern for irritation to all exposed tissues.

Environmental Hazard⁵: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent

persistent if it has a half-life in water, soil or sediments of greater than 2 months but less than or equal to 6 months or if there are equivalent or analogous data. A chemical substance is considered to be very persistent if it has a half-life in water, soil or sediments of greater than 6 months or there are equivalent or analogous data. (64 FR 60194; November 4, 1999)

³ Bioaccumulation. A chemical substance is considered to have a low potential for bioaccumulation if there are bioconcentration factors (BCF) or bioaccumulation factors (BAF) of less than 1,000 or there are equivalent or analogous data. A chemical substance is considered to be bioaccumulative if there are BCFs or BAFs of 1,000 or greater and less than or equal to 5,000 or there are equivalent or analogous data. A chemical substance is considered to be very bioaccumulative if there are BCFs or BAFs of 5,000 or greater or there are equivalent or analogous data. (64 FR 60194; November 4 1999)

⁴ A chemical substance is considered to have low human health hazard if effects are observed in animal studies with a No Observed Adverse Effect Level (NOAEL) equal to or greater than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have moderate human health hazard if effects are observed in animal studies with a NOAEL less than 1,000 mg/kg/day or if there are equivalent data on analogous chemical substances; a chemical substance is considered to have high human health hazard if there is evidence of adverse effects in humans or conclusive evidence of severe effects in animal studies with a NOAEL of less than or equal to 10 mg/kg/day or if there are equivalent data on analogous chemical substances. In the absence of animal data on a chemical or analogous chemical substance, EPA may use other data or information such as from in vitro assays, chemical categories^{6,7}, structure-activity relationships, and/or structural alerts to support characterizing human health hazards.

A chemical substance is considered to have low ecotoxicity hazard if the Fish, Daphnid and Algae LC50 values are greater than 100 mg/L, or if the Fish and Daphnid chronic values (ChVs) are greater than 10.0 mg/L, or there are not effects at saturation (occurs when water solubility of a chemical substance is higher than an effect concentration), or the log Kow value exceeds QSAR cut-offs. A chemical substance is considered to have moderate ecotoxicity hazard if the lowest of the Fish, Daphnid or Algae LC50s is greater than 1 mg/L and less than 100 mg/L,

TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0044 & 0045

upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using the Ecological Structure Activity Relationships (ECOSAR) Predictive Model (https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model). Based on these estimated hazard values, EPA concludes that these chemical substances have low environmental hazard.⁶

Potential Exposures: The exposure to a new chemical substance is potentially relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated worker exposure to the new chemical substances via the dermal and inhalation routes and general population exposure via drinking water and fish ingestion. EPA could not quantify risk due to insufficient toxicity data but believes that exposure to the general population will be low and is unlikely to result in unreasonable risk, and EPA expects that workers will use adequate personal protective equipment. Consumer exposure is not expected.

Potentially Exposed or Susceptible Subpopulation(s): Workers are potentially exposed. Given that EPA expects workers to use adequate dermal protection (including impervious gloves, eye protection, and protective clothing), EPA finds that these chemical substances are not likely to present unreasonable risk to workers.

3/23/2018	/s/
Date:	Jeffery T. Morris, Director
	Office of Pollution Prevention and Toxics

or where the Fish or Daphnid ChVs are greater than 0.1 mg/L and less than 10.0 mg/L. A chemical substance is considered to have high ecotoxicity hazard, or if either the Fish, Daphnid or Algae LC50s are less than 1 mg/L, or any Fish or Daphnid ChVs is less than 0.1 mg/L (Sustainable Futures https://www.epa.gov/sustainable-futures-p2-framework-manual).

Organization for Economic Co-operation and Development, 2014 Guidance on Grouping of Chemicals, Second Edition. ENV/JM/MONO(2014)4. Series on Testing & Assessment No. 194. Environment Directorate, Organization for Economic Co-operation and Development, Paris, France. (http://www.oecd.org/officialdocuments/publicdisply documentpdf?cote=env/jm/mono(2014)4&doclanguage=en)

⁶ TSCA New Chemicals Program (NCP) Chemical Categories (https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf)

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 4/12/2019 9:40:58 AM

To: Lynn L. Bergeson [lbergeson@lawbc.com]

Subject: RE: Follow Up

Lynn,

Please submit the proposed modification to the consent order through the normal process. It will then go through the typical review and management chain. Please keep me apprised of your progress.

Thanks,

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com

Sent: Wednesday, April 10, 2019 7:54 PM **To:** Baptist, Erik <Baptist.Erik@epa.gov>

Subject: Follow Up

Good evening Erik,

Our client is nearing a point of no return. Any update on this?

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Friday, March 22, 2019 3:50 PM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Hello Erik,

Rich and I spoke with you back in February (see below). When we spoke, we offered to suggest consent Order language to address the commercial reality of our client's (as well as other clients) need to distribute a PMN substance that has a invited a SNUR (but none has been issued in final) to its customer and its customer's need to distribute further the PMN substance, and the limitations in the Consent Order disallowing such further distribution. The appended suggests

language to address this situation, while still providing EPA with the information it seeks to track the distribution of the substance. The PMN substance at issue here is P-17-0172.

We would be pleased to discuss.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

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40 CFR §721.45 provides:

The persons identified in §721.5 are not subject to the notification requirements of §721.25 [SNUN requirements] for a chemical substance identified in subpart E [a specific SNUR] of this part, unless otherwise specified in a specific section in subpart E, if:

- (h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:
 - 1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
 - 2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the

substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

We would be happy to discuss. We suspect we are not alone in seeking guidance on this issue as supply chains today are more complicated than the "single distribution" language contemplates.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbe.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 4/11/2019 3:05:00 PM

To: Lynn L. Bergeson [lbergeson@lawbc.com]

Subject: RE: Follow Up

I'm planning to discuss with OPPT at our new chemicals meeting today.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com

Sent: Wednesday, April 10, 2019 7:54 PM **To:** Baptist, Erik <Baptist.Erik@epa.gov>

Subject: Follow Up

Good evening Erik,

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LYNN L. BERGESON MANAGING PARTNER

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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Friday, March 22, 2019 3:50 PM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Hello Erik,

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We would be pleased to discuss.

Thanks

LYNN L. BERGESON MANAGING PARTNER BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 3/26/2019 3:20:32 PM

To: Lynn L. Bergeson [lbergeson@lawbc.com]

Subject: RE: Follow Up

Yes, just a little overwhelmed at the moment. Is it time sensitive? I plan to review this week.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com

Sent: Tuesday, March 26, 2019 8:55 AM **To:** Baptist, Erik <Baptist.Erik@epa.gov>

Subject: FW: Follow Up

Hi Erik,

Trust you saw this.

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbe.com

From: Lynn L. Bergeson

Sent: Friday, March 22, 2019 3:50 PM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Hello Erik,

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LYNN L. BERGESON

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2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

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BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 2/28/2019 11:38:42 AM

To: Lynn L. Bergeson [lbergeson@lawbc.com]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]

Subject: RE: Follow Up

Yes please.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com Sent: Thursday, February 28, 2019 6:33 AM To: Baptist, Erik Baptist, February 28, 2019 6:33 AM

Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>

Subject: RE: Follow Up

Ok. Call your office?

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbe.com

From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Thursday, February 28, 2019 6:27 AM

To: Lynn L. Bergeson **Cc:** Richard E. Engler, Ph.D. **Subject:** RE: Follow Up

Great – let's plan for 2:30.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson < lbergeson@lawbc.com>
Sent: Thursday, February 28, 2019 6:25 AM

To: Baptist, Erik < Baptist. Erik@epa.gov>

Cc: Richard E. Engler, Ph.D. < rengler@lawbc.com>

Subject: RE: Follow Up

Sure, I am free after 2:30. Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Thursday, February 28, 2019 6:24 AM

To: Lynn L. Bergeson **Cc:** Richard E. Engler, Ph.D. **Subject:** RE: Follow Up

Let's plan to discuss tomorrow afternoon, if that works for you.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson < lbergeson@lawbc.com Sent: Wednesday, February 27, 2019 5:53 AM To: Baptist, Erik Baptist.Erik@epa.gov

Cc: Richard E. Engler, Ph.D. < rengler@lawbc.com>

Subject: Follow Up

Erik,

Would you have any opportunity to discuss this any time soon?

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Good Morning Erik,

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(h) The person submits a significant new use notice for the substance prior to the promulgation date of the section in subpart E of this part which identifies the substance, and the person receives written notification of compliance from EPA prior to the effective date of such section. The notice submitter must comply with any applicable requirement of section 5(b) of the Act. The notice must include the information and test data specified in section 5(d)(1) of the Act and must be submitted on the notice form in Appendix A to part 720 of this chapter. For purposes of this exemption, the specific section in subpart E of this part which identifies the substance and §§721.1, 721.3, 721.11, 721.35, and 721.40 apply; after the effective date of the section in subpart E of this part which identifies the substance, §721.5 applies and §721.20 continues to apply. EPA will provide the notice submitter with written notification of compliance only if one of the following occurs:

- 1. EPA is unable to make the finding that the activities described in the significant new use notice will or may present an unreasonable risk of injury to health or the environment under reasonably foreseeable circumstances.
- 2. EPA and the person negotiate a consent order under section 5(e) of the Act, such order to take effect on the effective date of the section in subpart E of this part which identifies the substance.

We would expect EPA to push back with a concern that the submitter (of the significant new use notice in this fact pattern) many not actually be engaging in a significant new use as envisioned in 721.45 (h), because the SNUN describes operating under the conditions specified in the consent order, and conclude this interpretation of 721.45(h) and the SNUN are invalid. In addition, EPA's approval of a SNUN submitted by the customer's customer would not change the prohibition in the consent order against further distribution. The customer's customer may be permitted to receive the substance as a result of EPA's action under 721.45(h), but the submitter's customer is still bound by the prohibition against further distribution. Conversely, if the submitter's customer submits a SNUN under 721.45(h), it is not clear how such a submission would bind the customer's customer.

We question whether 721. 45(h) allows the further distribution of a PMN substance as outlined above as suggested by the attorney-advisor. We recognize that even if this interpretation were deemed colorable, we would likely need OGC sign off.

Are we missing anything? Are there other options to permit distribution in supply chains that are more complex than just a manufacturer and direct customer, such as modifying consent orders to permit further distribution as long as written agreements are in place throughout the supply chain?

We would be happy to discuss. We suspect we are not alone in seeking guidance on this issue as supply chains today are more complicated than the "single distribution" language contemplates.

Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 2/28/2019 11:26:40 AM

To: Lynn L. Bergeson [lbergeson@lawbc.com]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]

Subject: RE: Follow Up

Great - let's plan for 2:30.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com Sent: Thursday, February 28, 2019 6:25 AM To: Baptist, Erik Baptist, Erik <a href="mailto:lbergeson@lawbc.

Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>

Subject: RE: Follow Up

Sure, I am free after 2:30. Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Baptist, Erik [mailto:Baptist.Erik@epa.gov]
Sent: Thursday, February 28, 2019 6:24 AM

To: Lynn L. Bergeson **Cc:** Richard E. Engler, Ph.D. **Subject:** RE: Follow Up

Let's plan to discuss tomorrow afternoon, if that works for you.

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson < lbergeson@lawbc.com Sent: Wednesday, February 27, 2019 5:53 AM

To: Baptist, Erik < Baptist. Erik@epa.gov>

Cc: Richard E. Engler, Ph.D. < rengler@lawbc.com>

Subject: Follow Up

Erik,

Would you have any opportunity to discuss this any time soon?

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

Good Morning Erik,

We suspect EPA OPPT has received similar requests from others, but we wanted to run this scenario by you. We have a number of clients who have signed consent orders and are finding that the delay in promulgating final SNURs is a formidable barrier to the commercialization of the new chemical substances.

As you know, EPA consent orders allow distribution of a PMN substance to the submitter's direct customer provided the end-user agrees in writing to abide by the restrictions of the consent order and to not further distribute the PMN substance. The prohibition against further distribution automatically sunsets 75 days after the promulgation of a SNUR for the substance. The problem arises between the time when the consent order is signed and when the SNUR is published in final. An OPPT attorney-advisor has suggested that a submitter's customer's customer may submit a SNUN under 40 CFR Section 721.45(h) to allow the submitter's customer to distribute further a PMN substance once the SNUR is proposed but before it is published in final.

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LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbe.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 2/28/2019 11:24:03 AM

To: Lynn L. Bergeson [lbergeson@lawbc.com]
CC: Richard E. Engler, Ph.D. [rengler@lawbc.com]

Subject: RE: Follow Up

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Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Lynn L. Bergeson lbergeson@lawbc.com Sent: Wednesday, February 27, 2019 5:53 AM To: Baptist, Erik Baptist, Erik <a href="mailto:lbergeson@lawbc

Cc: Richard E. Engler, Ph.D. <rengler@lawbc.com>

Subject: Follow Up

Erik,

Would you have any opportunity to discuss this any time soon?

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Lynn L. Bergeson

Sent: Tuesday, February 12, 2019 8:55 AM

To: Erik Baptist, Esquire **Cc:** Richard E. Engler, Ph.D.

Subject: Follow Up

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Thanks

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 2/22/2019 3:05:33 PM

To: Starr, Richard [Richard_Starr@americanchemistry.com]

Subject: Re: GlobalChem 2019: TSCA Risk Management

11:30-12:30 or after 4.

Sent from my iPhone

On Feb 22, 2019, at 8:59 AM, Starr, Richard < Richard Starr@americanchemistry.com > wrote:

Thanks Tabby and Mark for your availability today.

Erik, are you available sometime today for a brief call to talk about our session?

Richard Starr | American Chemistry Council Manager, Regulatory & Technical Affairs richard starr@americanchemistry.com 700 2nd Street, NE | Washington, DC | 20002 O: (202) 249-6443 C: (202) 580-9494 www.americanchemistry.com

From: Starr, Richard

Sent: Thursday, February 21, 2019 8:05 AM **To:** 'Mark Duvall'; 'Waqar, Tayyaba'; 'Baptist, Erik'

Cc: Blanco, Susan

Subject: GlobalChem 2019: TSCA Risk Management

Hi All,

Thank you for agreeing to speak at our TSCA Risk Management session on March 7th, at 3:00 PM. The session description is below. A couple items for each of you:

- 1. <!--[if !supportLists]--><!--[endif]-->I'd like to schedule a call so that everyone can discuss what they'd like to present for the session. Please let me know your **availability for tomorrow**, if possible. Note that I will be moderating your panel, and will come up with a few key questions for each of you, which I will share a few days prior to our session.
- 2. <!--[if !supportLists]--><!--[endif]-->If you plan to use a powerpoint presentation, please send it to Susan Blanco (copied) as soon as you can, but no later than March 4th.
 - a. <!--[if !supportLists]--><!--[endif]-->Please also send Susan a short bio and a headshot so that we can display your information for attendees in the session.
- 3. <!--[if !supportLists]--><!--[endif]-->Our session is planned for one hour, and usually there are about 10 or so minutes set aside at the end of each session for Q&A. This means that individual presentations usually last about 15 minutes, depending on how we would like to split up the topics.
- 4. <!--[if !supportLists]--><!--[endif]-->You will each be registered for the full conference, so when you arrive, make sure you get your badge from the registration desk.

5. <!--[if !supportLists]--><!--[endif]-->If you have any questions in the meantime, don't hesitate to contact me at my cell phone number below.

Thank you again!

TSCA Risk Management: Updates and what to expect:

EPA has various tools to undertake risk management under TSCA for both new and existing chemicals. This session will offer a brief overview of where risk management has been implemented historically, what some of the legal challenges have been to risk management, and an update on how EPA is using its new authorities under amended TSCA to take on risk management activities. Our panelists will also offer observations and insights on trends in the New Chemicals program and proposals and activity under Section 6 for existing chemicals. The panel will conclude with observations on how an understanding of risk management under Section 5 can help inform what might be yet to come under Section 6.

Richard Starr | American Chemistry Council Manager, Regulatory & Technical Affairs richard starr@americanchemistry.com
700 2nd Street, NE | Washington, DC | 20002 O: (202) 249-6443 C: (202) 580-9494 www.americanchemistry.com

Message

From: Baptist, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10FC1B085EE14C6CB61DB378356A1EB9-BAPTIST, ER]

Sent: 2/9/2019 8:55:59 PM

To: Starr, Richard [Richard_Starr@americanchemistry.com]; Schmidt, Karyn [Karyn_Schmidt@americanchemistry.com]

CC: Bolen, Derrick [bolen.derrick@epa.gov]

Subject: RE: GlobalChem Conference

Richard,

Thank you for your email. Yes, I am interested in joining this session. Let's find a time this coming week to discuss. I am copying my colleague Derrick Bolen, who can assist with both scheduling our call and confirming with EPA ethics that I can participate.

Best,

Erik Baptist

Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-1689
baptist.erik@epa.gov

From: Starr, Richard < Richard_Starr@americanchemistry.com >

Sent: Friday, February 8, 2019 9:25 AM

To: Schmidt, Karyn < Karyn_Schmidt@americanchemistry.com>; Baptist, Erik < baptist.erik@epa.gov>

Subject: RE: GlobalChem Conference

Hi Erik, I just wanted to follow up with you to confirm your interest in joining this session. Below is a full description of the session. Please let me know if you'd like to set up a time to chat more about this. Thanks!

TSCA Risk Management: Updates and what to expect:

EPA has various tools to undertake risk management under TSCA for both new and existing chemicals. This session will offer a brief overview of where risk management has been implemented historically, what some of the legal challenges have been to risk management, and an update on how EPA is using its new authorities under amended TSCA to take on risk management activities. Our panelists will also offer observations and insights on trends in the New Chemicals program and proposals and activity under Section 6 for existing chemicals. The panel will conclude with observations on how an understanding of risk management under Section 5 can help inform what might be yet to come under Section 6.

Richard Starr | American Chemistry Council Manager, Regulatory & Technical Affairs richard_starr@americanchemistry.com
700 2nd Street, NE | Washington, DC | 20002
O: (202) 249-6443 C: (202) 580-9494
www.americanchemistry.com

From: Schmidt, Karyn

Sent: Tuesday, February 5, 2019 12:45 PM

To: Baptist.erik@Epa.gov

Cc: Starr, Richard

Subject: GlobalChem Conference

Good afternoon Erik. ACC is now planning the panels for the upcoming GlobalChem conference in early March, http://www.cvent.com/events/2019-globalchem-conference-exhibition/event-summary-

<u>b2685a905d65401a9317899c533b5300.aspx</u>, and we are inclined to add a TSCA risk management panel. As we have been planning this panel, we believe the substantive discussion would very much benefit from a legal perspective, and we wanted to reach out to you to discuss the possibility of you participating.

I have copied Richard Starr on this email. Richard is leading the planning of the session, and he can provide additional information on this proposed panel and answer any questions you might have. The conference will be held in Washington DC at the Omni Shoreham.

Thank you for your consideration.

Karyn Schmidt Senior Director, Regulatory & Technical Affairs American Chemistry Council 202-249-6130

Message

From: Morris, Jeff [Morris.Jeff@epa.gov]

Sent: 3/23/2019 11:51:23 AM

To: Kathleen M. Roberts [kroberts@lawbc.com]

CC: lbergeson@lawbc.com; Beck, Nancy [Beck.Nancy@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Henry,

Tala [Henry.Tala@epa.gov]; Wormell, Lance [Wormell.Lance@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]

Subject: RE: TSCA NCC - Letter on EPA Practice for SNUR rulemakings and White Paper - Consideration of 'Nonrisk' Versus

'Risk' Factors Under Toxic Substances Control Act Section 5

Kathleen,

Thank you very much for the letter and white paper from the New Chemicals Coalition. We will review the material and reach out to you if we have any questions or believe that follow-up with the NCC is needed.

All the best,

Jeff

Jeffery T. Morris, PhD
Director, Office of Pollution Prevention & Toxics
US Environmental Protection Agency

1200 Pennsylvania Avenue, NW (MC-7401M) Washington, DC 20460

(202) 564-3810

From: Kathleen M. Roberts < kroberts@lawbc.com>

Sent: Friday, March 22, 2019 3:59 PM **To:** Morris, Jeff < Morris.Jeff@epa.gov>

Cc: lbergeson@lawbc.com; Beck, Nancy <Beck.Nancy@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov> Subject: TSCA NCC - Letter on EPA Practice for SNUR rulemakings and White Paper - Consideration of 'Nonrisk' Versus

'Risk' Factors Under Toxic Substances Control Act Section 5

Jeff:

Appended is a letter from the Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC) requesting a change in the current U.S. Environmental Protection Agency (EPA) practices regarding direct final rulemakings for Significant New Use Rule (SNUR) notices impacting multiple chemicals (document number 258856).

Also appended for your consideration is a white paper prepared by the TSCA NCC on the "Consideration of 'Nonrisk' Versus 'Risk' Factors Under Toxic Substances Control Act Section 5" (document number 252550).

If it would be helpful, we would be pleased to meet with you and your staff to discuss these documents further.

KATHLEEN M. ROBERTS VICE PRESIDENT

B&C CONSORTIA MANAGEMENT LLC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-833-6581 | F: 202-557-3836 | bc-cm.com

Message

From: Kathleen M. Roberts [kroberts@lawbc.com]

Sent: 3/22/2019 7:58:34 PM

To: Morris, Jeff [Morris.Jeff@epa.gov]

CC: lbergeson@lawbc.com; Beck, Nancy [Beck.Nancy@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]

Subject: TSCA NCC - Letter on EPA Practice for SNUR rulemakings and White Paper - Consideration of 'Nonrisk' Versus 'Risk'

Factors Under Toxic Substances Control Act Section 5

Attachments: 00258856.pdf; 00252550.pdf

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White Paper: Consideration of "Nonrisk" Versus "Risk" Factors Under Toxic Substances Control Act Section 5

March 22, 2019

Introduction

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), "unreasonable risk" is to be determined "without consideration of costs or other nonrisk factors," (referred to as the "without consideration' phrase" in this paper). This amended language appears in TSCA Sections 5, 6, 9, and 21; interestingly, it does not appear in Section 4. This paper explores the application of the term "nonrisk factors" to new chemical determinations and regulatory actions under Section 5.

Legislative History

The term "nonrisk factors" appears to have been introduced as an amendment to the Senate bill, S. 697, by Senator Jim Inhofe (R-OK) in 2015¹ where the term appeared in the definition of "safety standard" at Section 3(16), and remained in the bill when the Senate passed S. 697 by unanimous consent in December 2015.² The term was retained in the compromise text between the House and Senate in May 2016,³ although its usage was somewhat different. The compromise text did not retain the Section 3 definition of safety standard and the "without consideration" phrase generally appeared in the context of the U.S. Environmental Protection Agency (EPA) assessing chemical risks (Sections 9 and 21) and specifically regarding conducting a risk evaluation to determine unreasonable risk under Section 6(b). The phrase was also included in Section 5(a)(3)(B)(ii)(I) concerning reviewing and making a determination on a new chemical and in Section 5(e) of amended TSCA concerning regulatory actions to prohibit or limit commercial activities "to the extent necessary to protect against an unreasonable risk."

{01508.001 / 111 / 00252550.DOCX 17}

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Available at https://www.epw.senate.gov/public/_cache/files/e56cfb54-bef6-4625-ba0d-590af2a40c73/s.697---inhofe-substitute---10-21-15-.pdf.

TSCA Reform -- Compromise Text, available at https://archives-energycommerce.house.gov/files/document-s/114/analysis/20160520TSCASummary.pdf.



White Paper: Consideration of "Nonrisk" Versus "Risk" Factors Under TSCA Section 5 March 22, 2019 Page 2

Discussion of Role of "Risk" Versus "Nonrisk" Factors in TSCA Section 5

Within this section there are three references to "unreasonable risk" and all include the "without consideration" phrase that includes the term "nonrisk factors." The first is at Section 5(a)(3)(B)(ii)(I) and pertains to the EPA review and determination that a new chemical "may present an unreasonable risk." The latter references appear in Section 5(e). The first of these is in Section 5(e)(1)(A)(ii)(I) and essentially cross references the determination of "may present an unreasonable risk" made under Section 5(a)(3)(B)(ii)(I), while the second reference pertains to the "extent necessary" consideration in imposing an order under Section 5(e). While these references can be read as disallowing consideration of "costs or other nonrisk factors" in making a determination or in imposing an order, they cannot be interpreted as disallowing consideration of "risk factors."

EPA, however, appears to be interpreting "nonrisk factors" as precluding consideration of any factors beyond the risk per se of the notified new chemical in isolation in making its determination of unreasonable risk or issuing an order to the extent necessary to protect against the unreasonable risk. By doing so, EPA goes beyond the text and, as a matter of policy, restricts its ability to weigh "risk factors" such as the potential risk of the new chemical compared to the risk of an existing chemical that the new chemical is intended to replace. This policy position, beyond clearly exceeding the statutory text, presents a variety of disincentives and challenges to a new chemical innovator looking to market a safer, greener replacement chemical. While the new chemical may not be risk-free, it could be relatively or even far safer than the incumbent, existing chemical when the panoply of risk factors such as toxicity, exposure potential, persistence, bioaccumulation, release, susceptibility to treatment, and others are considered. Such risk factors can take the form of pollution prevention benefits (lower toxicity, lower potential for releases and exposures, and less persistence in the environment), energy efficiency (reduced contribution to global warming; lower operating temperatures and pressures that contribute to worker safety) or process efficiency (lesser amounts needed to achieve similar or superior performance with resultant lower material needs and lower exposure potential), or provide other positive risk attributes relative to the existing chemical products.

As a matter of law and as part of an overall goal of safety, EPA should be including such risk-based comparisons as part of its determination as well as part of its decision to take "extent necessary" actions under Section 5(e). Prior to the passage of Lautenberg, EPA did include relative risk considerations in its decisions about premanufacture notices (PMN) but, at the moment, this does not appear to be occurring. In addition, by avoiding consideration of a risk



White Paper: Consideration of "Nonrisk" Versus "Risk" Factors Under TSCA Section 5 March 22, 2019 Page 3

comparison of the new chemical with the existing chemical, EPA is imposing barriers to technological innovation, which is contrary to TSCA's policy statement at Section 2(b)(3).

Most "new chemical" products are not entirely new but are chiefly intended to improve on the functionality and performance of existing chemicals by commercializing new chemicals that are more efficient, have better processing options, have better performance, and are less toxic. The net result of these factors is strong continuous improvement. Increased efficiency in manufacturing, processing, and use also translates into less material being used and less material being released into the environment, which is the very essence of pollution prevention. The availability of better processing options, including equal or improved performance at lower temperatures, leads to reduced energy usage and potentially safer work environments. These are goals TSCA was intended to achieve, and represent what EPA should be attempting to support and encourage as part of the Section 5 chemical review process. In fact, many of the risk-based factors discussed above are directly relatable to, if not the same as, the considerations brought to bear in applying the Sustainable Futures program tools to new chemicals and are referenced within EPA's own definition of green chemistry.⁴

Discussion/Proposal

It is not clear to us why there is a question about the applicability of risk factors in making determinations and in considering and taking regulatory action on new chemicals. EPA is urged to consider carefully the text in Section 5 and to clarify the role of the elements that relate to a comparison of risks between new and existing chemical alternatives and to confirm that such a comparison is not precluded as a "nonrisk factor." In our view, such comparisons are within the scope of what can and should be considered by innovators when developing new chemicals and by EPA in its "may present" determinations and in consideration of "extent necessary" in taking action to control new chemicals. If a new chemical submitter provides relevant information in the Pollution Prevention (P2) section of the PMN, including information based on Sustainable Futures tools, EPA should have a systematic approach to consider that information and include these as risk-based factors in its decisions under Section 5. Indeed, if information is provided as to how the new chemical represents a risk-based improvement relative to an existing chemical, EPA's determination of potential risk for that new chemical should include consideration of

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EPA, Basics of Green Chemistry, Definition of green chemistry, available at https://www.epa.gov/greenchemistry/basics-green-chemistry#definition.



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potential risk if the new chemical does not proceed to or is disadvantaged in the market, and the existing chemical remains.

We urge EPA promptly to consider the points raised in this paper. We believe there are strong arguments that EPA is not barred from, rather, it is required to consider risk-based factors in making determinations under Section 5(a)(3)(B)(ii)(I) and in taking regulatory decisions under Section 5(e). Further, assuming that EPA agrees with the conclusions offered, we urge prompt action to communicate this understanding to stakeholders. This should include encouraging notifiers of new chemicals that are still in review, including those in voluntary suspension, to develop and submit information regarding risk-based factors for EPA's consideration, and the development of EPA guidance for use by future notifiers. We believe that the existing guidance for Sustainable Futures and for the voluntary Pollution Prevention (P2) page provides an excellent start for such an effort.



March 22, 2019

Via E-Mail

Jeffery T. Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Dear Jeff

The Toxic Substances Control Act (TSCA) New Chemicals Coalition (NCC)¹ requests that the U.S. Environmental Protection Agency (EPA) change its current practices regarding direct final rulemakings for Significant New Use Rule (SNUR) notices impacting multiple chemicals to be in compliance with relevant provisions under the Code of Federal Regulations (C.F.R.). Our reasons for requesting this change are set forth below.

We are aware of and grateful for EPA staff's efforts to address the backlog of SNURs that exists and appreciate EPA's approach to issue direct final SNURs for multiple chemicals in one *Federal Register* notice. An unfortunate consequence of this approach, however, is EPA's current practice that the submission of an adverse comment on one or a few of the SNURs listed in the notice means that all of the SNURs in the notice are withdrawn. Thus, even SNURs for which no adverse comment has been submitted are withdrawn and subject to potentially long delays and significant adverse market implications before final rules can be issued for such chemicals.

We note that this EPA practice is not consistent with 40 C.F.R. Section 721.160(c)(3)(ii) and 40 C.F.R. Section 721.170(d)(4)(i)(B) concerning direct final rulemaking on "5(e)" and "non5(e)" SNURs, respectively, which states as follows:

{01508.001 / 111 / 00225160.DOCX 9} 2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 | T: <u>202-557-3801</u> | F: <u>202-557-3836</u>

The TSCA NCC is a group of company representatives focused on working collaboratively with EPA to resolve issues of concern related to new chemical review under amended TSCA.



...The written notice of intent to submit adverse or critical comments should state which SNUR(s) will be the subject of the adverse or critical comments, if several SNURs are established through the direct final rule. If notice is received within 30 days that someone wishes to submit adverse or critical comments, the section(s) of the direct final rule containing the SNUR(s) for which a notice of intent to comment was received will be withdrawn by EPA issuing a document in the final rule section of the FEDERAL REGISTER.

This procedure is also specified in the final rule implementing the direct final rule procedure:

EPA intends as much as possible to include more than one SNUR in a single Federal Register document to provide administrative efficiencies and save publication costs. With respect to direct final rulemaking procedures, when EPA publishes a number of SNURs in a single Federal Register document as direct final SNURs, the person notifying EPA of intent to submit adverse or critical comments will be asked to indicate to which SNUR the comments will apply. EPA would then publish a notice in the final rule section of the Federal Register withdrawing only that specific direct final SNUR and publish a separate proposal for that specific SNUR. However, EPA would not withdraw the direct final SNURs which are unaffected by the person's wish to submit adverse or critical comments.²

Delaying the effective date of SNURs for which no adverse or critical comments were submitted is inconsistent with the policy objectives of the direct final SNUR procedures as specified by EPA in its final rule and regulations, which EPA stated is intended to "expedite" promulgation of

² 54 Fed. Reg. 31298, 31305 (July 27, 1989).



SNURs with "the objective of providing prompt promulgation of SNURs to follow-up on new chemical substances."

Furthermore, we do not believe that the current practice whereby some commenters offer a generic statement that the comments apply to all of the SNURs as proposed meets the requirements outlined in these C.F.R. provisions as it does not provide a clear basis for determining that an adverse comment has been submitted for all of the subject chemicals in the SNUR. 40 C.F.R. Sections 721.160(c)(3)(ii) and 721.170(d)(4)(i)(B) make clear that the adverse comments need to be specifically attached to a given SNUR(s) and that only those SNUR(s) are subject to withdrawal.

Consistent with 40 C.F.R. Section 721.160(c)(3)(ii) and 40 C.F.R. Section 721.170(d)(4)(i)(B), we request that EPA promulgate in the C.F.R. all past direct final SNURs for which no adverse comment specific to that SNUR was submitted. We understand that EPA is required to review any adverse comments submitted on the batched SNURs, but the TSCA NCC respectfully requests that this review occur as quickly as reasonably possible. We urge that EPA focus initially on identifying SNURs that were not the subject of specific adverse comment. We make this request due to the significant adverse market implications for those chemicals not implicated by any adverse comment but for which SNURs have not yet been issued in final.

In a related matter, the TSCA NCC has observed how the legal effect of SNURs for both new and existing chemicals has been widely misunderstood and mischaracterized by stakeholders and the general public. The recent asbestos SNUR is a good example. In the general and trade press, it has been characterized by some as "allowing" new asbestos uses. This, as you know, is an erroneous and misleading statement of the purpose and effect of a SNUR. Considering the changes in amended TSCA Section 5(a) that now require EPA to review a significant new use notification (SNUN), make a determination, and take the actions required in association of that determination, we encourage EPA to develop and use a clearer and legally accurate characterization of the effect of SNURs in its written materials, including in *Federal Register* notices that propose or promulgate SNURs, including expedited SNURs. We offer the following suggestions as ways to characterize more clearly the legal effect of SNURs and defend against intentional or unintentional mischaracterization of SNURs:

__

³ *Id.* at 31299.



- The SNUR identifies conditions of use that are prohibited absent EPA review of a notification that such use is contemplated and its determination that such use can proceed and, if so, under what circumstances.
- The legal effect of a SNUR is to prohibit subject conditions of use absent completion of the steps required by Section 5(a). These requirements include submission to EPA of a notification, followed by EPA's review and determination under Section 5(a)(3) on the notified significant new uses, and any EPA actions required in association with that determination. Absent a determination that the significant new use is "not likely to present an unreasonable risk," EPA is required to regulate to the extent necessary to protect against such risk.

Thank you for your consideration of the legal and policy arguments raised in this letter. We would appreciate an opportunity to meet with you and other EPA staff to discuss the specific recommendations outlined above. I will contact you in the near future to identify potential meeting dates.

Sincerely,

Kathleen M. Roberts

cc: Nancy B. Beck, Ph.D., DABT (via e-mail) Alexandra P. Dunn, Esquire (via e-mail)

Via E-Mail

Jeffery T. Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Statutory Mixtures and Mixed Metal Oxides

Dear Dr. Morris:

Appended is a letter responding to the U.S. Environmental Protection Agency's (EPA) December 27, 2017, letter to our client relating to mixed metal oxides and statutory mixtures. As you know, our clients, individually and as part of the Statutory Mixture Group, have engaged EPA in a discussion regarding EPA's guidance on statutory mixtures and its applicability to mixed metal oxides. To ensure your easy access to all of our correspondence on this topic, we also append the related correspondence between Bergeson & Campbell, P.C. (B&C®) and EPA:

- Letter from B&C to Kevin McLean, Esq., March 4, 2016;
- Letter from B&C to Kevin McLean, Esq., April 6, 2016;
- Letter from Kevin McLean, Esq., to B&C, October 7, 2016;
- Letter from B&C to Jeffery Morris, Ph.D., May 10, 2017;
- Letter from B&C to Jeffery Morris, Ph.D., July 31, 2017; and
- Letter from Jeffery Morris, Ph.D. to B&C, December, 27 2017.

We look forward to EPA's response.

Sincerely,

Lynn L. Bergeson Richard E. Engler, Ph.D.

Attachments

cc: Tracy C. Williamson, Ph.D. (via e-mail) (w/attachments)
Donald Sadowsky, Esquire (via e-mail) (w/attachments)
Brian P. Grant, Esquire (via e-mail) (w/attachments)

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May 22, 2018

<u>Via</u> E-Mail

Jeffery T. Morris, Ph.D.
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Statutory Mixtures and Mixed Metal Oxides

Dear Dr. Morris:

We write in response to your letter dated December 27, 2017, regarding the U.S. Environmental Protection Agency's (EPA) guidance on statutory mixtures¹ and its applicability to mixed metal oxides (MMO). We appreciate your continued attention to this important matter, but respectfully disagree with the Agency's interpretation and legal analysis.

Although not explicitly stated by the U.S. Environmental Protection Agency (EPA), we interpret the term "statutory mixtures" to refer to cases in which a chemical reaction occurs during the formation of a product and, nevertheless, EPA considers the product to be a "mixture." Statutory mixtures are products that do not meet the definition of mixtures that result from blending substances that do not react (as described in Section III.A. of the Mixture Guidance). For clarity we refer herein to these mixtures as "simple mixtures." Our view on the eligibility of MMOs is independent of the difference between "statutory" and "simple" mixtures. We use these terms in the following discussion, but are <u>not</u> seeking more specificity about EPA's interpretation of either a "statutory" or a "simple" mixture. We only seek clarity on what products may be eligible to be considered a mixture.

In your December letter, you state that "in the Agency's guidance on mixtures, an MMO is actually a single chemical substance that is the chemical product of the reaction occurring between the reactants used to manufacture the MMO." We interpret this to mean that, in EPA's view, no MMO is eligible to be considered a statutory mixture. Further, you state "[b]ecause each distinct MMO is a chemical substance representing a particular chemical composition as actually manufactured, any MMO that is not already specifically listed on the Inventory is subject to PMN reporting where not exempt." While these statements are quite definitive in their declaration that any and all MMOs are ineligible for the statutory mixture

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EPA, Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures (Mixtures Guidance), available at https://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf.



exemption, we find no support for this position in the Mixture Guidance or elsewhere. One might reach this conclusion based on what may not be considered to be a mixture (simple or statutory), but there is no declarative statement to this effect in the Mixture Guidance or other Toxic Substances Control Act (TSCA) Inventory guidance.

The letter supports its contention by citing Example 8 of EPA's guidance on chemical substances of Unknown or Variable composition, Complex reaction products and Biological materials (UVCB)² in which *rutile, neodymium* is used as example of an inorganic substance that is a UVCB. We agree that this substance qualifies as an MMO. As EPA is aware, however, there are many cases in which a manufacturer has discretion on how a substance is represented for Inventory purposes. The fact that EPA (or another manufacturer) represents an MMO as a UVCB does not prevent a manufacturer from describing its product, even one that might be indistinguishable from an analytic standpoint from the UVCB product, as a mixture of multiple substances. In fact, the opposite is true: EPA guidance explicitly permits a manufacturer to identify a product as either a mixture or a complex substance in certain circumstances. In its guidance for naming alkyl range substances, EPA states:

A substance named with a broad alkyl range is considered to be on the Inventory if every specific substance within the range is independently on the Inventory. The broadly-named substance would be duplicative of the sum of the individual ones and so does not require its own Inventory listing.

This language permits a manufacturer to identify a product as a substance with an alkyl range (e.g., alcohols, C6-9) or as a mixture of the alcohols that would make up that range (i.e., hexanol, heptanol, octanol, and nonanol) as long as each of the individual constituents is independently listed on the Inventory. Similarly, EPA's UVCB Guidance states:

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EPA, Toxic Substances Control Act Inventory Representation for Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials: UVCB Substances (UVCB Guidance), available at https://www.epa.gov/sites/production/files/2015-05/documents/uvcb.pdf.

EPA, Toxic Substances Control Act Inventory Representation for Certain Chemical Substances Containing Varying Carbon Chain Lengths (Alkyl Ranges Using the CX-Y Notation) (Alkyl Range Guidance), available at https://www.epa.gov/sites/production/files/2015-05/documents/alkyl-rg.pdf.



A reaction product combination could, in theory, be named as either a group of individual Class 1 substances (if all of the individual molecules in the product are known and always present) or as a Class 2 UVCB complex reaction product.

Again, this language explicitly permits a manufacturer to identify a product as a UVCB substance or a mixture of individual substances. Clearly a manufacturer has discretion as to how it identifies a product regardless of how others might identify the same product for purposes of listing on the Inventory. The fact that an MMO is listed on the Inventory or that an MMO appears in the UVCB Guidance in no way prohibits a manufacturer from identifying an MMO product as a mixture.

In your December 27 letter, you also state that MMOs are "not actually mentioned or described in the guidance." We agree that the term "mixed metal oxide" does not explicitly appear in the Mixture Guidance, but Example 10 describes a "mixed oxide catalyst" that contains only metals (cobalt and aluminum) and oxygen. It is an intuitively logical leap to refer to the substance described in Example 10 as a "mixed metal oxide."

Your December 27 letter goes on to state that Examples 8, 9, and 10 of the Statutory Mixture Guidance are "not statutory mixtures." We cannot reconcile this statement with the plain text of the Mixture Guidance in which the heading of Part III.B. is titled "Combinations that are considered to be statutory mixtures under TSCA." Examples 8, 9, 10 are all in Part III.B. We thus are at a loss to understand how <u>none</u> of these examples qualifies as a statutory mixture.

Subsection III.B.1. discusses "[c]ertain alloys, inorganic glasses, ceramics, frits and cements, including Portland cement" and specifically states that each is considered to be a statutory mixture by the Agency. Subsection III.B.2. discusses "[c]ertain combinations of metals, inorganic metal compounds and inert supports, which are frequently used for commercial purposes, including for use as solid phase heterogeneous catalysts, are also considered to be mixtures for the purposes of the TSCA Inventory." While this statement does not specifically state that the examples that follow (*i.e.*., Examples 8, 9, and 10) are statutory mixtures, the subsection is still included in Part III.B. which does explicitly state that the subsections (*i.e.*, III.B.1 and III.B.2.) relate to "combinations that are considered to be statutory mixtures."

The letter goes on to discuss that Examples 8, 9, and 10 "discuss other kinds of mixtures that are not statutory mixtures." EPA interprets our July 2017 letter to mean that the Statutory Mixture Group interprets each of the Examples in Subsection III.B.2 as MMOs. We regret the confusion. In our view, Example 8 applies to supported catalysts, Example 9 applies to zeolites, and Example 10 applies to MMOs. We included interpretations of Examples 8 and 9

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to refute EPA's earlier contention (in its October 7, 2016, letter) that Subsection III.B.2 only applies if one of the substances in question is an "inert support."

The common thread for each of these examples is that in each a chemical reaction occurs, the resultant product does not meet the definition of a simple mixture, and EPA nevertheless views the product to be a mixture (a statutory mixture, by our definition). While one can debate whether a supported catalyst meets the definition of a simple mixture or a statutory mixture, a zeolite cannot be considered a simple mixture. Zeolites are aluminosilcates consisting of extended networks of aluminum, silicon, and oxygen bound with polar covalent bonds. There may be regions of a zeolite that are largely aluminates and regions that are largely silicates, depending on the ratio of aluminum and silicon used to manufacture the zeolite, but these regions are not necessarily separate and distinct; overall zeolites are a network of aluminum and silicon atoms covalently linked by oxygen atoms. The distribution of silicon and aluminum will be a function of the molar ratios, synthetic templates, and manufacturing conditions.4 As the Mixture Guidance states, "[t]he final zeolites are characterized by covalently linked AlO₄ [aliminate] and SiO₄ [silicate] tetrahedra." Many MMOs are analogous to zeolites, in that the MMOs, like zeolites, consist of covalent networks of metals connected by oxygen atoms. In our view, it is entirely reasonable to view Example 9 as supporting the interpretation that Example 10 can be broadly applied for purposes of identifying MMOs as mixtures of the individual metal oxides (or of the starting materials used to manufacture the MMO).

Given EPA's standard nomenclature practices, zeolites would be considered to be substances except for the operation of Example 9 in which EPA states that zeolites are considered to be mixtures. Furthermore, Example 9 states that "[z]eolites as a class of substances are considered mixtures under TSCA regardless of the commercial manufacturing processes and reactants utilized to achieve the desired chemical composition of the final zeolite structure" and that "[t]he application of EPA's guidance is not affected by the chemical composition of the zeolite under consideration." Clearly, EPA views zeolites to be mixtures regardless of what starting materials are used to manufacture the product as long as the products are aluminosilicates. The Mixture Guidance calls out this product formed by a chemical reaction that results in a complex combination of covalently bound aluminum, silicon, oxygen, and other atoms, and identifies the product as a mixture. There is no interpretation that would qualify a zeolite as a simple mixture. Even in the simplest form, reacting alumina (or an aluminate salt) with silica (or a silicate salt) is manufacturing an aluminosilicate zeolite substance. Conversely, the Mixture Guidance does not prohibit a manufacturer from identifying the product as a substance. In fact, aluminosilicate (Chemical Abstracts Service (CAS) Registry Number (RN)

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Cejka, J. and Kubicka, D. (2010). Zeolites and other Micro- and Mesoporous Molecular Sieves in *Kirk-Othmer Encyclopedia of Chemical Technology*, 1.



1327-36-2) is listed on the Inventory. A manufacturer of a product that is a combination of alumina and silica could either identify the product as a substance with CAS RN 1327-36-2 or as a mixture of the starting materials used to manufacture that product, as specified in the Mixture Guidance.

Your December letter states that the heading of Section III.B. of the Mixture Guidance "is unfortunate since it could be interpreted that all of the examples discussed in parts 1 and 2 are statutory mixtures." We regard this statement as supporting our contention that there is and continues to be substantial uncertainty about the interpretation of the mixture guidance. We again request that EPA update its guidance on the applicability of the Mixture Guidance (as it did with activated phosphors) and/or permit manufacturers to rely upon reasonable interpretations that have been used since the Mixture Guidance was published in 1995. We strongly disagree with EPA's statement that "the Agency has provided consistent interpretation of the guidance on mixtures to explicate the various parts."

As we have discussed in previous correspondence, there is a long history of confusion about the applicability of the Mixture Guidance and your December 27 letter in no way clarifies the matter. In fact, the December 27 letter is not consistent with EPA's previous letter on the matter (dated October 7, 2016), which interpreted Examples 8, 9, and 10 as being mixtures, but only in limited circumstances (such as when the product is a catalyst with an inert support). EPA's two written responses to us on this topic muddy the waters considerably with regard to EPA's interpretation, which regrettably is now quite incoherent. We again urge EPA to take the necessary steps to update its Mixture Guidance to reflect EPA's current thinking. If such an update necessitates a number of PMNs, EPA should provide for continued production of existing MMO products while PMNs are prepared and reviewed.

We look forward to EPA's response.

Sincerely,

Lynn L. Bergeson Richard E. Engler, Ph.D.

cc: Tracy C. Williamson, Ph.D. (via e-mail)
Donald Sadowsky, Esquire (via e-mail)
Brian P. Grant, Esquire (via e-mail)

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March 4, 2016

Via E-Mail

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Office of General Counsel
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Dear Kevin:

We are writing on behalf of a coalition of companies that produce mixed metal oxides to request a meeting with the Office of General Counsel (OGC) to discuss the legal implications of when the U.S. Environmental Protection Agency (EPA) applies new nomenclature approaches for determining what is a "chemical substance" or a "mixture," as those terms are used in the Toxic Substances Control Act (TSCA). By our reading, these new approaches do not flow from, and are inconsistent with, existing regulations and long-standing guidance. We believe that the application by EPA of its new, apparently preferred nomenclature approach is generating unnecessary irregularities in the interpretation and legal administration of TSCA, and that avoidable disputes and costly litigation are the likely consequence unless EPA adopts more rational, systematic, transparent, and fair procedures.

In recent years, EPA has often utilized more specific nomenclature approaches to decide whether a chemical substance is included on the TSCA Inventory that is compiled pursuant to TSCA Section 8(b), 15 U.S.C. § 2607(b). This more specific nomenclature may differ from the nomenclature routinely utilized by manufacturers or processors of the chemical substance at the time EPA compiled the TSCA Inventory and in intervening years. In particular, EPA, without public notice regarding changes to this existing body of regulations and guidance, now prefers to describe certain chemical substances comprised of complex combinations of differing molecules in a manner that differs from the descriptions of the same heterogeneous chemical substances that were accepted and relied upon by EPA when the Inventory was originally compiled, as well as over the intervening decades by industry as it applied EPA's guidance for such substances. We see no reason why EPA cannot adopt a more specific nomenclature approach now, but it should provide proper notice and establish a rational, systematic, transparent, and fair procedure for updating nomenclature guidance as well as updating the names of substances listed on the TSCA Inventory to conform to that nomenclature system.

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Kevin W. McLean, Esquire March 4, 2016 Page 2

Unfortunately, in some recent instances, EPA has chosen to apply a more specific nomenclature for chemical substances without establishing such a procedure. Instead, EPA has characterized some existing chemical substances that were in commerce when EPA originally compiled the TSCA Inventory as "new" chemical substances, thereby causing a variety of serious legal irregularities and practical problems in the administration of TSCA.

The most prominent example of this emerging problem is the nomenclature that EPA now utilizes for complex combinations of chlorinated paraffins. EPA decided that the less specific nomenclature for these substances used in the current TSCA Inventory is unsatisfactory. Rather than providing a rational procedure to amend the Inventory to conform to the more specific nomenclature it prefers, EPA elected to require Premanufacture Notices (PMN) based on the curious thesis that various substances that have been in commerce for decades are "new." As a result, the manufacturers and importers of a number of complex combinations of chlorinated paraffins have submitted PMNs, even as manufacture and importation of these same substances has continued. This extra-statutory hybrid procedure (imposing new chemical notification requirements under TSCA Section 5 for substances that EPA acknowledges are already in commerce) has created substantial confusion about which sections of TSCA can be lawfully used to regulate the substances in question. This hybrid procedure will result in disputes and litigation that could have been avoided if EPA had undertaken a procedure to revise the listings in the existing TSCA Inventory to conform to the new nomenclature.

Moreover, we think the problems with chlorinated paraffins are just the tip of a very large iceberg. We are aware of numerous other instances where complex chemical substances have been and are being actively distributed in commerce based on an existing broad listing in the TSCA Inventory, although that listing may not conform to the more specific nomenclature that apparently EPA now prefers. These chemical substances are typically derived from petrochemical feedstocks and are variable and complex combinations of many discrete substances. If EPA elects to raise legal questions about every one of these existing complex chemical substances, and does not establish a procedure other than submission of PMNs to amend the TSCA Inventory, new legal irregularities and further litigation are inevitable.

Similarly, it appears that the evolving approach to nomenclature may also be affecting the way EPA construes the statutory definition of a "mixture," which is excluded from the definition of a "chemical substance" and, thus, need not be included in the TSCA Inventory. EPA has recently reviewed several PMNs for mixed metal oxides that, based on published EPA guidance as discussed below, would logically have been construed as a mixture not requiring submission of a PMN. We are uncertain whether this is because EPA has now concluded that mixed metal oxides no longer meet the definition of a mixture under "Products Containing Two or More Substances: Formulated and Statutory Mixtures" (Mixture Guidance). We note that

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See http://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf.



Kevin W. McLean, Esquire March 4, 2016 Page 3

Example 10 in that guidance clearly states that the formation of a mixed metal oxide is considered a mixture. We recognize that some PMN submitters may elect to use a single identity to characterize a substance that is eligible to be considered a mixture based on the submitter's specific commercial intent. It is not clear to us whether the submitters of the recent PMNs for substances in this category are taking this approach voluntarily, as a result of enforcement action, or from fear of such action.

We believe there is considerable potential for disruption if EPA does not establish a rational, systematic, and fair procedure for amending the Inventory to conform to its new interpretation. There is no reason why EPA cannot create a rational procedure for incrementally implementing the new interpretation. EPA undertook just such an effort when it updated its interpretation of doped phosphors. EPA provided notice, including its rationale for changing the nomenclature guidance, and an opportunity for stakeholders to comment. 73 Fed. Reg. 2854 (Jan. 16, 2008). EPA published its final guidance and provided manufacturers a window in which they could continue to manufacture or import their products while submitting PMNs. 75 Fed. Reg. 8266 (Feb. 24, 2010). Dozens of phosphors have since been added to the TSCA Inventory. Implementing such a new interpretation for mixed metal oxides presents significant legal and commercial issues and adds additional support to the view that EPA needs to create a rational procedure for implementing the new interpretation.

We are not suggesting that EPA cannot periodically update the nomenclature system that it uses to classify chemical substances and mixtures under TSCA to require greater specificity, to resolve ambiguities, or to implement new interpretations or policies. Rather, we are suggesting that consequential legal and commercial implications flow from even seemingly incremental changes in nomenclature that should be identified and explained. EPA should create a procedure for amending the Inventory to conform to the new nomenclature that does not create statutory irregularities or unfairly penalize those who rely on the validity of existing Implementing nomenclature changes in the context of enforcement nomenclature guidance. actions is inappropriate because it randomly and arbitrarily imposes retroactive liability on parties that have lawfully relied on the validity of the existing nomenclature guidance. It is also inefficient, because it will lead inevitably to protracted and costly litigation. imposing new nomenclature interpretation in the context of enforcement actions does not provide appropriate notice and transparency to other manufacturers who rely on the same guidance, particularly when EPA determinations concerning chemical identity may be contingent on confidential composition information. Such action is analogous to pulling over a car travelling at the posted speed limit, citing the driver for exceeding a new, unpublicized, lower speed limit, and not informing any other drivers of the new lower limit.



Kevin W. McLean, Esquire March 4, 2016 Page 4

We are hopeful that OGC can encourage EPA to use rational, systematic, transparent, and fair procedures to update the TSCA Inventory when EPA's preferred nomenclature for describing chemical substances or mixtures evolves. We are concerned that the current methods for implementing nomenclature changes do not provide appropriate notice or transparency, and that these methods will create unnecessary statutory irregularities, foster legal disputes, and promote costly litigation. We look forward to discussing these issues with you.

Sincerely,

Lynn L. Bergeson

cc: Avi S. Garbow, Esquire (via e-mail)

April 6, 2016

Via E-Mail

Kevin W. McLean, Esquire Associate General Counsel Pesticides and Toxic Substances Law Office Office of General Counsel U.S. Environmental Protection Agency William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 2333A Washington, DC 20460

Dear Kevin:

We are writing on behalf of the Mixed Metal Oxides Common Interest Group to thank you for meeting with us and with representatives of the member companies on March 30, 2016, to discuss U.S. Environmental Protection Agency (EPA) guidance concerning inclusion of mixed metal oxides on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory (Inventory) compiled by EPA pursuant to TSCA Section 8(b)(1), and the procedures that EPA should utilize if it decides, in its discretion, to alter or clarify the existing guidance. We appreciate the time you and your colleagues devoted to us, believe that the meeting was constructive, and hope that you agree.

As we stated several times during the meeting, it is not our objective to constrain the ability of EPA to adopt revised nomenclature for chemical substances that must be listed on the Inventory, or to prevent EPA from revising its guidance concerning the inclusion of categories of chemical substances like "statutory mixtures" on the Inventory. Rather, it is our view that EPA should provide proper notice when it decides to adopt or to implement any new nomenclature or guidance that will be used in deciding whether a product is already listed on the TSCA Inventory. EPA should establish a procedure for implementing any new nomenclature or guidance that is rational and transparent, and that does not unfairly penalize those manufacturers or users who have relied in good faith, for decades, on the previous nomenclature or guidance. If EPA representatives argue that nomenclature or guidance that has clearly evolved, or is evolving, is actually static, or if EPA characterizes a discretionary change in policy or interpretation as a non-discretionary scientific determination, such an interpretation is neither rational nor transparent. Such an approach is also fundamentally unfair to those parties who have relied in good faith on the prior nomenclature or guidance.

We are requesting that EPA confirm that the existing guidance concerning "statutory mixtures" in the 1995 guidance document entitled "Toxic Substances Control Act

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www.lawbe.com



Kevin W. McLean, Esquire April 6, 2016 Page 2

Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures" is still in effect. Specifically, the members of the Mixed Metal Oxides Common Interest Group would like EPA to clarify whether Example 10 on page 6 of that guidance still represents EPA policy, and whether each mixed metal oxide product that is like the hypothetical product in Example 10 would still be a type of mixture that may be represented by the separate metal oxide listings on the Inventory.

In addition, if EPA guidance or policy on the characterization of mixed metal oxides has changed or is changing, we request that EPA confirm that it will utilize a procedure to effectuate any change similar to the procedure that EPA utilized when it updated its guidance concerning the characterization of doped phosphors. In that instance, EPA provided notice including its rationale for changing its nomenclature guidance, and provided an opportunity for affected stakeholders to comment. 73 Fed. Reg. 2854 (Jan. 16, 2008). EPA then published final guidance and provided manufacturers a "safe harbor" period in which they could continue to manufacture or import their products while submitting any newly required Premanufacture Notifications (PMN). 75 Fed. Reg. 8266 (Feb. 24, 2010).

EPA adopted a similar approach in 2008 when, on October 31, 2008, EPA provided notice in the *Federal Register* that it generally considers carbon nanotubes to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA Inventory. EPA helpfully also stated that some time "after March 1, 2009, EPA anticipates focusing its compliance monitoring efforts to determine if companies are complying with TSCA section 5 requirements for carbon nanotubes." This notice effectively provided regulated entities a "safe harbor" period of five months to address the consequences of EPA's notification. 73 Fed. Reg. 64946.

We note that when EPA does not utilize this type of transparent process to update its preferred nomenclature or policy concerning listings in the Inventory, serious anomalies arise. Implementing nomenclature or guidance changes in the context of enforcement actions or threats of enforcement can arbitrarily impose retroactive liability on parties that have relied in good faith, and for decades, on the validity of previous nomenclature or guidance. We need look no further than the curious position EPA and industry find themselves in in connection with medium and long chain chlorinated paraffins and their regulatory status under TSCA as a result of *Dover Chemical* and related enforcement actions. A less transparent process is also inefficient, because it will likely lead to protracted and costly litigation, including disputes concerning whether the proper vehicle for any substantive regulation of a product is TSCA Section 5 or TSCA Section 6. These costly disputes, and the commercial chaos they cause, can be prevented by avoiding random enforcement actions that, by their very nature, disproportionately impact selected

See http://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf.



Kevin W. McLean, Esquire April 6, 2016 Page 3

regulated entities and, as we discussed during our meeting, invite concerns regarding regulation by enforcement.

We hope that our discussion of the current EPA guidance concerning characterization of mixed metal oxide products at the March 30, 2016, meeting was helpful, and we look forward to your response. Thank you again for providing an opportunity for us to discuss our concerns about potential changes in the nomenclature or policy for mixed metal oxide products, and the correct procedure for effectuating any change in that nomenclature or policy that EPA may be considering. We are attaching for your convenience the documents distributed at the meeting. As for the compendium of documents assembled in the spiral binder, we attach here the index. If you would like the electronic version of all of these documents, please let us know.

Sincerely,

Mywh

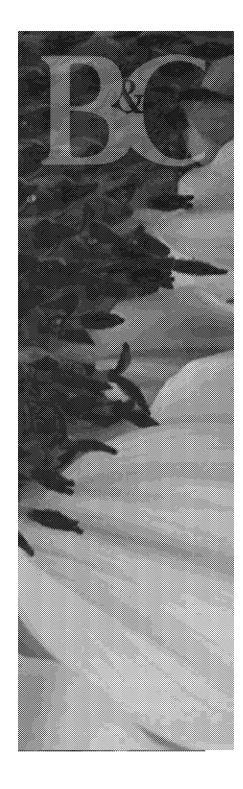
Lynn L. Bergeson Timothy D. Backstrom

Attachments

cc: Maria J. Doa, Ph.D. (w/ attachments) (via e-mail)

Donald Sadowsky, Esquire (w/attachments) (via e-mail) Brian P. Grant, Esquire (w/ attachments) (via e-mail)

Mr. Kenneth T. Moss (w/ attachments) (via e-mail)



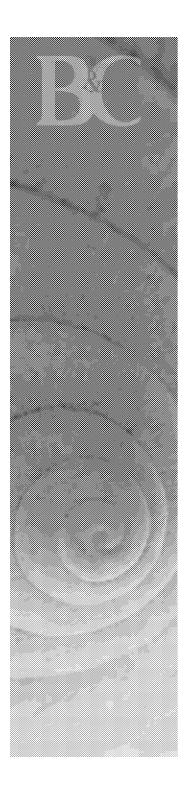
BERGESON & CAMPBELL PC

Procedures for Revision of Current EPA Guidance Concerning Inclusion of Mixed Metal Oxides Products on the TSCA Inventory

Meeting Between
U.S. Environmental Protection Agency
Office of General Counsel
and
Mixed Metal Oxides Common Interest Group

March 30, 2016

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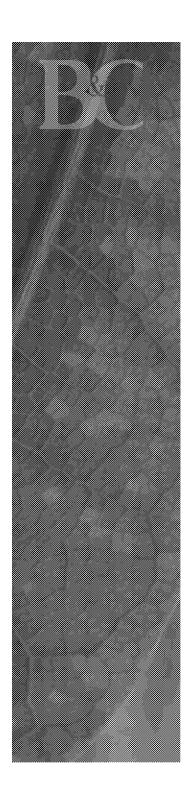
Requirement of Inclusion on the TSCA Inventory

- A "new chemical substance" is any chemical substance not included on the Toxic Substances Control Act (TSCA) Inventory compiled by the U.S. Environmental Protection Agency (EPA) pursuant to TSCA Section 8(b)(1)
- No new chemical substance can be manufactured or processed in the U.S. unless the manufacturer or processor submits a premanufacture notice (PMN) pursuant to TSCA Section 5(a)(1)
- Under TSCA, a "mixture" is a combination of two or more substances that does not occur in nature and is not the result of a chemical reaction, except that a combination of substances that is the result of a chemical reaction may be deemed to be a mixture if each of the substances is included on the TSCA Inventory and the combination could be manufactured without a chemical reaction
- A mixture under TSCA is not considered to be a chemical substance, and need not be listed on the TSCA Inventory prior to manufacture or processing



Inclusion of "Statutory Mixtures" on the TSCA Inventory

- EPA recognized there were some instances where a combination of chemical substances has long been in commerce, even though the combination results from a chemical reaction and is not or may not be a mixture as defined under TSCA
- EPA has also recognized that it may not be practical to characterize every substance included in such a combination
- To address this situation, EPA identified six chemical categories and stated that the substances produced during the manufacture of products in these categories do not need to be identified separately and reported for TSCA purposes:
 - Portland Cement
 - Alumina Cement
 - Glass Oxides
 - Frits
 - Steel Manufacture Chemicals
 - Ceramic Materials and Wares
- These six listed categories are generally referred to as "statutory mixtures," although this may be confusing because any combination of discrete chemical substances that are deemed to be a TSCA mixture need not be listed on the TSCA Inventory at all
- EPA has occasionally suggested a narrower construction of the listing for statutory mixtures, including questioning whether all substances included in such a combination that result from the chemical reaction are reportable or if a chemical reaction nullifies eligibility to be identified as a mixture
- These categories have led to significant confusion and discussion, as evidenced by the decade-long history of communication between the Office of Pollution Prevention and Toxics (OPPT) and industry stakeholders



EPA Guidance Concerning "Statutory Mixtures"

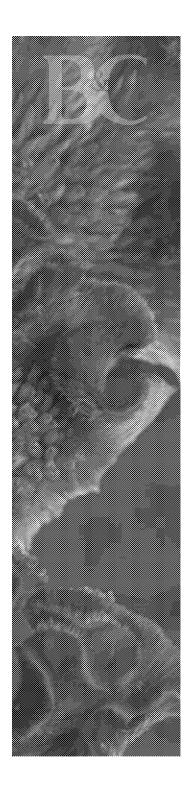
- In 1995, EPA issued detailed guidance describing the legal intent and practical implications when a combination of chemical substances is included in a statutory mixtures category. See EPA, Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures (1995 Guidance)
- In addition to the statutory mixtures categories, the 1995 Guidance identifies other examples of statutory mixtures, including supported catalysts, zeolites, and mixed metal oxides
- The 1995 Guidance also identifies other examples of mixtures, including hydrates and surface treatment of solids. In these cases, the guidance *explicitly* states that these mixtures are either a mixture of the starting materials (*e.g.*, zeolites, hydrates) or a mixture of the resultant individual products (*e.g.*, supported catalysts, mixed metal oxides)
- EPA has never withdrawn or modified the 1995 Guidance

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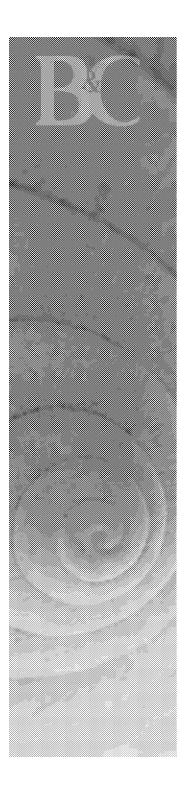
Mixed Metal Oxides Products Are Statutory Mixtures

- There are a number of products currently in commerce that consist of combinations of metal oxides
- In general, these products are composed of chemical substances that are individually listed on the TSCA Inventory
- Example 10 in the 1995 Guidance expressly affirms that mixtures of metal oxides formed by a chemical reaction are considered to be a mixture of the individual metal oxides, and that new, "more complex" substances "which may be formed incidentally in the manufacture of the catalyst mixture" would not require a PMN
- Manufacturers and importers have marketed mixed metal oxides products for many years, based both on the inclusion of the individual oxides on the current TSCA Inventory and in the 1995 Guidance



Doped Phosphors Are Not Mixtures

- EPA determined that doped phosphors, a complex combination of metal oxides, sulfides, nitrides, and carbides with small amounts of additives, often called dopants, are not mixtures, but chemical substances that fall outside of the 1995 Guidance
- EPA proposed this clarification in 2008, 73 Fed. Reg. 2854 (Jan. 16, 2008), provided for notice and comment, and published its final determination in 2010, 75 Fed. Reg. 8266 (Feb. 24, 2010)
- EPA articulated its rationale and the criteria that differentiates doped phosphors from other statutory mixtures, and implemented a procedure involving submission of PMNs for such chemical substances



Recent PMNs for Mixed Metal Oxides Products

- We were under the impression that the status of mixed metal oxides products as statutory mixtures was clear, but recent PMNs cause us to wonder whether prior suggestions that the statutory mixtures should be construed more narrowly than in the 1995 Guidance are being pursued again by EPA
- PMN submitters have discretion to elect to identify a substance with a unique identity even though that substance is eligible to be considered a statutory mixture of the individual metal oxides
- If these PMNs do not reflect a discretionary decision by the submitters to submit a notification for a substance that could be identified as a statutory mixture of two or more already listed substances, then these PMNs may indicate that EPA is interpreting guidance inconsistently to what is stated in the 1995 Guidance
- Although EPA has no legal discretion to delete any statutory mixtures category from the TSCA Inventory once it is listed, we are concerned that EPA may be pursuing a new policy concerning the definition of statutory mixtures



Changing the Policy Set Forth in the 1995 Guidance

- We are not suggesting that EPA cannot adopt new nomenclature that could include a new construction of the scope of statutory mixtures when it interprets the meaning of the TSCA Inventory
- We believe that fundamental fairness requires prior notice to affected parties explaining the changed nomenclature or construction, along with a reasonable transitional process to effectuate the new nomenclature or construction
- The correct approach when EPA decides to adopt a new construction of the meaning or scope of the 1995 Guidance concerning an Inventory listing is exemplified by the procedure EPA used to revise its interpretation of doped phosphors
- EPA provided notice and an opportunity to comment before changing its policy, and then allowed an 18-month window during which manufacturers could submit any newly required PMNs
- We recognize that the Supreme Court recently held that notice and opportunity for comment are not mandatory when an agency changes its prior guidance, but this precedent does not mean that EPA has no obligation to provide notice and an opportunity to come into compliance for those who have relied, potentially to their detriment, on EPA's existing published guidance



Thank You

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Mixed Metal Oxide PMNs After 1/1/2013

Case No.	Received	Submitter	Use	Chemical Name	ပ္သ	Notes
			(S) Piezoelectric ceramics used for	(S) Lead Strontium Titanium		
P-11-0270	3/21/2011	Lockheed Martin	active and passive underwater	Zirconium Oxide	S	MMO
P-12-0245	3/20/2012	The Shepherd Color	(S) Colored pigment used	(S) Niobium sulfur tin zinc oxide	S	
		Company				MMO-like
		Praxair Specialty	(G) Catalysts used in closed	(G) Lanthanide group, groupiia, mn,		
P-13-0195	1/3/2013	Ceramics.	processes	oxide		SWO SWO
		Praxair Specialty	(G) Catalysts used in closed			
P-13-0196	1/3/2013	Ceramics.	processes	(G) Ni, lanthanide group, oxides		MMO
P-13-0373	4/5/2013	CBI	(S) Battery material	(G) Mixed metal oxide.		AMO OMBO
P-14-0146	12/11/20 3	CBI	(G) Component Of Lighting And Personal Digital Devices	(G) Mixed metal fluoride silicide*		phosphor-like
P-14-0256	1/15/2014	CBI	(S) Led Lighting Applications	(S) Aluminum Yttrium Oxide, Cerium- Doped	: '	phosphor
P-14-0262	1/17/2014	CBI	(S) Led Lighting Applications	(S) Barium Europium Nitrogen Silicon		phosphor
P-15-0328	3/3/2015	a	/G) Cement additive	(G) Aluminum calcium oxide salt		MMO-like
P-15-0328	3/3/2015	<u> </u>	(G) Cement additive	(G) Aluminum calcium oxide salt		MMO-like
P-15-0450	5/4/2015	B	(G) Mixed metal oxide for batteries	(G) Lithium mixed metal oxide		MWO
P-15-0525	6/10/2015	CBI	(G) Catalyst	(G) Rare earth doped zirconium oxide		MMO-like
D 15 0526	8/10/2015	ā	(G) Catalyst	(G) Rare earth doped zirconium oxide		MMO-like
	200000000000000000000000000000000000000		(G) Catalyst	Opin Born and deposit in oxide		MMO-like
P-15-0527	6/10/2015	CBI	(G) Catalyst	(G) Rare earth doped zirconium oxide		MMO-like
P-15-0582	7/8/2015	<u></u>	(G) Intermediate	(G) Doped Zirconium Oxide		MMO-like
P-15-0612	7/15/2015	BrandWatch Technologies	(S) Additive for brand protection and anticounterfeiting inks and polymers	(S) Sulfur thullum ytterbium yttrium oxide	ပ္သ	phosphor
P-15-0613	7/15/2015	BrandWatch Technologies	(S) Additive for brand protection and anticounterfeiting inks and polymers	(S) Gadolinium sulfur ytterbium yttrium oxide, erbium- and thulium- doped	ပ NON	phosphor

P-15-0614 7/15/2015	7/15/2015	BrandWatch	(S) Additive for brand protection and	(S) Neodymium sulfur yttrium oxide.	<u>N</u> 00	
		Technologies	anticounterfeiting inks and polymers			phosphor
P-15-0615	7/15/2015	BrandWatch	(S) Additive for brand protection and	(S) Erbium gadolinium neodymium	Noc	
		Technologies	anticounterfeiting inks and polymers	sulfur ytterbium yttrium oxide.		phosphor
P-15-0616	7/15/2015	BrandWatch	(S) Additive for brand protection and	(S) Erbium gadolinium sulfur	<u>S</u>	
		Technologies	anticounterfeiting inks and polymers	ytterbium yttrium oxide.		phosphor
P-15-0617	7/15/2015	BrandWatch	(S) Additive for brand protection and	(S) Erbium gadolinium ytterbium	<u>လ</u>	
		Technologies	anticounterfeiting inks and polymers	oxide.		phosphor
P-15-0618	7/15/2015	BrandWatch	(S) Additive for brand protection and	(S) Erbium gadolinium sulfur	<u> </u>	
		Technologies	anticounterfeiting inks and polymers	lytterbium oxide.		phosphor
P-15-0620	7/17/2015	BO	(G) Catalyst	(G) Doped Zirconium Oxide		MMO-like
P-16-0017	10/8/2015	Alcoa, Inc.	(S) Blast suppressor for nitrogen	(G) Mixed metals layered double		MO-ike
			based fertilizers	hydroxide*		
			(G) Coating component	(G) Mixed metal oxide-halide		
P-16-0086	11//11/2015 CBI	80		complex.		MMO-like
•		The Shepherd Color	(G) Pigment for anti-corrosive paints	(S) Aluminum vanadium zinc		
P-16-0120	12/8/2015	Company		hydroxide oxide		MMO
P-16-0191	1/22/2016	The Shepherd Color	(G) Pigment for anti-corrosive paints	(S) Aluminum vanadium zinc		MMO
		Company		hydroxide oxide		



Meeting Between
U.S. Environmental Protection Agency
Office of General Counsel
And
Mixed Metal Oxides Common Interest Group

March 30, 2016

phone: 202,557,3800 fax: 202,557,3836



Index

- 1. August 4, 2006, Letter from G. McCarney, 3M, to K. Anapolle, OPPT Industrial Chemistry Branch with questions regarding TSCA Section 8(b)(2) categories. Copy not available.
- 2. September 18, 2007, Letter from Tracy Williamson, Chief, OPPT Industrial Chemistry Branch to G. McCarney, 3M, stating EPA did not intend for the Section 8(b)(2) categories to determine inventory status for any actual chemical substances.
- 3. November 26, 2007, Letter from M. Walls, ACC, to T. Williamson, OPPT, demonstrating the September 18, 2007, letter was inconsistent with TSCA and prior agency guidance and requesting its withdrawal.
- 4. May 28, 2008, Letter from T. Williamson, OPPT, to M. Walls, ACC, stating the Section 8(b)(2) category listings should not be used to cover chemically manufactured products for TSCA Inventory and reporting purposes.
- 5. August 29, 2008, Letter from M. Walls, ACC, to J. Gulliford, OPPT, requesting withdrawal of the May 28, 2008, letter and meeting.
- 6. October 8, 2008, Meeting of ACC representatives with R. Lee, Director, OPPT Economics, Exposure and Technology Division, and others in that Division.
- 7. November 12, 2008, Meeting of DuPont Microcircuit Materials representative with R. Lee, OPPT and members of his staff. Copy not available.
- 8. December 22, 2008, Letter from R. Lee, OPPT, to M. Walls, ACC, stated EPA was discussing the possibility of developing a clarification notice.
- 9. June 9, 2009, Letter from Walls, ACC, to R. Lee, OPPT, demonstrating that guidance for the 2006 TSCA IUR is consistent with historical industry understanding of the scope of the TSCA Section 8(b)(2) category listings.
- 10. July 21, 2009, Letter from R. Lee, OPPT, to M. Walls, ACC, acknowledging June 9, 2009, letter and stating EPA has formed a workgroup to clarify how EPA regards the Section 8(b)(2) categories, with publication of a draft notice expected in Fall 2009. Copy not available.
- January 2010, EPA posts its December 2009 Action Initiation List, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."

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- 12. Spring 2010 Regulatory Agenda, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."
- 13. Fall 2010 EPA Regulatory Plan and Semi-Annual Regulatory Agenda, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."
- 14. June 16, 2010, Letter from coalition of 13 trade associations and companies expressing concern regarding EPA's "apparent intent to delist" Section 8(b)(2) categories.
- 15. February 9, 2011, Meeting of ACC and OPPT to discuss TSCA categorical Inventory listings.
- 16. April 13, 2011, Letter from ACC to EPA OGC following up on February 9, 2011 meeting.
- 17. April 26, 2011, Meeting of ACC and member companies with OGC to discuss legal significance of TSCA categorical Inventory listings.
- 18. August 19, 2011, Letter from M. Walls, ACC to Wendy Cleland-Hamnett and Christine Kymn, OIRA, OMB opposing EPA's plan to issue a clarification for chemical identification in RIN 2070-AJ68.
- 19. June 2012, Unified Regulatory Agenda does not include RIN 2070-AJ68.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF GENERAL COUNSEL

October 7, 2016

Lynn L. Bergeson Timothy D. Backstrom Bergeson & Campbell PC 2200 Pennsylvania Avenue, NW, Suite 100W Washington, DC 20037-1701

Dear Lynn and Tim:

Thank you for your letters of March 4, 2016 and April 6, 2016, and coming to meet with us on March 30, 2016, regarding the treatment of substances you term "mixed metal oxides." EPA understands this term to refer to oxide substances containing two or more different metal species in the composition, with oxygen bonded in the oxide lattice to all the metals, such that a mixed metal oxide is considered a single chemical substance having a distinct molecular identity. You note in your March 4, 2016 letter that "EPA has recently reviewed several PMNs for mixed metal oxides," (twenty eight such PMNs were identified in your presentation of April 6), which you suggest should have instead been "construed as a mixture not requiring the submission of a PMN." In support of your view, you cite a 1995 EPA guidance document, titled *Products Containing Two or More Substances: Formulated and Statutory* Mixtures ("1995 Guidance"), and draw our attention in particular to Example 10 from the 1995 Guidance. In your April 6 letter you more specifically ask the Agency "to clarify whether Example 10 on page 6 of that guidance still represents EPA policy, and whether each mixed metal oxide product that is like the hypothetical product in Example 10 would still be a type of mixture that may be represented by the separate metal oxide listings on the Inventory."

EPA has not changed its interpretation of Example 10 since 1995. But it is impossible to give a simple yes-or-no answer to the question you have posed, because your question appears to be premised on a misunderstanding of the scope and meaning of Example 10.

Example 10 is located under heading Section III.B.2 of the 1995 Guidance: "Certain combinations of metals, inorganic metal compounds and inert supports, which are frequently used for commercial purposes, including for use as solid phase heterogeneous catalysts, are also considered to be mixtures for the purposes of the TSCA inventory."

The example reads as follows:

Example 10. Consider a cobalt oxide-aluminum oxide catalyst. A mixed hydroxide precipitate formed by the reaction of sodium hydroxide and an aqueous solution of cobalt (II) nitrate and aluminum nitrate is heated in air to

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Lynn L. Bergeson Timothy D. Backstrom October 7, 2016 Page 2

produce a mixed oxide catalyst. Some of the cobalt is known to be oxidized to Co(III) in the process. In this case, cobalt (II) oxide, cobalt (III) oxide and aluminum oxide would each be reported for the inventory. More complex compounds of cobalt and/or aluminum which may be formed incidentally in the manufacture of the catalyst mixture are not reported.

Example 10 is explicit in stating that the individual metal oxides (oxides based on just one metal species) created in the production of the catalyst would be reported for the Inventory. The one statement that involves not reporting for the Inventory is the last sentence: "More complex compounds of cobalt and/or aluminum which may be formed incidentally in the manufacture of the catalyst mixture are not reported." (emphasis added). Under the facts in Example 10, the overall composition was a mixture of reportable substances consisting of those with desired catalytic properties (cobalt (II) oxide, cobalt (III) oxide) and a catalyst support or carrier (an inert support (aluminum oxide), to which a catalyst is affixed), plus various non-reportable incidental compounds that served no intended purpose but could nonetheless be expected to arise at the interfaces between aluminum oxide, cobalt (II) oxide, and cobalt (III) oxide. The reportable substances of Example 10 are solely the individual metal oxides that are intended to be manufactured as a mixture of inert support and active catalyst.

incidental reaction products were exempted from the original compilation of the TSCA Inventory and have historically been exempted, by regulation, from various requirements under TSCA sections 8(a) and 5, including new chemical review requirements. This approach is consistent with EPA's explanatory statements in the preamble to the initial Inventory Rule, 42 FR 64585 (December 23, 1977) (rejecting arguments that "incidental reaction products," should be treated as mixtures rather than chemical substances, but nonetheless agreeing that such unintentionally formed chemical substances should be excluded from the Inventory). See also 40 CFR 710.4(d) and 40 CFR 720.30(h) (codifying this policy via exemptions for impurities, byproducts with no commercial purpose, and other unintended substances manufactured in certain other circumstances). It remains the case that incidentally-formed metal oxides are exempt from PMN requirements. Metal oxides that are not listed in the TSCA Inventory and are not incidentally manufactured remain subject to PMN requirements, unless exempt on some separate grounds.

Although it is not entirely clear from your question, you appear to be suggesting that Example 10 stands for the further proposition that any compounds consisting solely of metals and oxygen can be deemed to be already on the Inventory, by the theory that such chemical substances are somehow equivalent to a mixture of individual metal oxide substances, each of which is already listed individually on the Inventory. For example, you appear to be arguing that any intentionally produced compound consisting solely of aluminum, cobalt, and oxygen is insulated from Section 5 requirements due to the fact that aluminum oxide, cobalt (II) oxide, and cobalt (III) oxide are already listed on the TSCA Inventory.

EPA does not agree with this approach. Rather, each mixed metal oxide must itself be evaluated regarding whether it is on the TSCA Inventory. This is consistent with the Agency's interpretations set forth publicly in 1977. To interpret Example 10 otherwise would impute a superfluous rationale to the example (superfluous because Example 10 already gives a more straightforward rationale for its conclusion, described above). If the Agency had intended to establish a sui generis policy for treating mixed metal oxides, it would have done so plainly.

Lynn L. Bergeson Timothy D. Backstrom October 7, 2016 Page 3

Over the years, starting with the initial inventory reporting period, EPA has received approximately a thousand submissions identifying specific mixed metal oxides that the Agency has listed on the TSCA inventory. This indicates that it is already widely understood within industry that the potentially unlimited number of intentionally-generated metal oxide substances that could be synthesized from a particular set of atoms are not all equivalent to a single mixture of simple, individual metal oxides. There is no unfairness in holding companies to reporting rules that are clear and have been consistently administered throughout the implementation of TSCA.

Should you have any questions, please contact Don Sadowsky of my staff at 202-564-5638 or via email at sadowsky.don@epa.gov.

Sincerely,

Kevin McLean

Associate General Counsel

Pesticides and Toxic Substances Law Office

May 10, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Updating EPA Guidance Concerning on Inclusion of Formulated and Statutory Mixtures in TSCA Inventory

Dear Jeff:

We are writing as counsel for the Statutory Mixtures Group, a coalition of companies that manufacture or import products containing mixed metal oxides, to follow up on the several recent conversations you had with Lynn Bergeson concerning clarification of the U.S. Environmental Protection Agency (EPA) policy on formulated and statutory mixtures set forth in EPA's 1995 guidance document. There has been considerable discussion over the years between EPA and representatives of affected companies and trade associations concerning the construction and applicability of this guidance document. Of particular interest to the members of the Statutory Mixtures Group is Example 10 on page six of the 1995 Guidance, which addresses the applicability of Toxic Substances Control Act (TSCA) Inventory requirements to products containing mixed metal oxides.

We wrote to Kevin W. McLean, Associate General Counsel, on March 4, 2016, and April 6, 2016, to express our concern that the policy set forth in the guidance document appears to be evolving, and to request that EPA clearly articulate any revised policy and afford affected manufacturers an opportunity to come into compliance with that revised policy. We met with Messrs. McLean and Brian P. Grant and other EPA Office of Pollution Prevention and Toxics (OPPT) personnel on March 30, 2016, to discuss these matters. On October 7, 2016, Mr. McLean sent a letter to us addressing the issues discussed in our correspondence and at the March 30, 2016, meeting.

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EPA, "Products Containing Two or More Substances: Formulated and Statutory Mixtures" (1995 Guidance), available at http://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf.



In Mr. McLean's October 7, 2016, letter, he states that: "EPA has not changed its interpretation of Example 10 since 1995." Mr. McLean also posits that our concerns regarding EPA policy concerning products containing mixed metal oxides may be "premised on a misunderstanding of the scope and meaning of Example 10." We have carefully evaluated the discussion that follows, and we have concluded that this discussion leaves substantial uncertainty concerning interpretation of the 1995 Guidance in general and Example 10 in particular.

Mr. McLean's October 7, 2016, letter confirms that an intentionally created mixture of several metal oxides that are each individually listed in the TSCA Inventory can be a "statutory mixture" that need not be separately listed in the TSCA Inventory, and that the unintentional creation of "incidental reaction products" does not alter this conclusion. The letter rejects a broad construction of Example 10 that would include *all* intentionally created mixtures of metal oxides, but it does not provide any clear guidance on those specific characteristics that might cause EPA to conclude that an intentionally created mixture of metal oxides is not analogous to the mixture in Example 10 and therefore must be listed in the TSCA Inventory.

Respectfully, we think that the discussion in Mr. McLean's letter considered in context confirms the very concern around which our Group formed and clearly suggests that EPA policy concerning the construction of Example 10 has been evolving rather than static. Moreover, recent communications by individual members of the Statutory Mixtures Group with EPA representatives concerning the inclusion of particular mixed metal oxide products in the TSCA Inventory confirm this inference. Having said this, it has never been the view of the Statutory Mixtures Group or its individual members that EPA cannot revise or correct a prior construction of TSCA Inventory requirements. Rather, it is the Group's position that when EPA concludes it is necessary to revise or to correct such a construction, EPA must publish an explanation of the revised or corrected policy and afford an opportunity for affected stakeholders to comment. Moreover, if a revised or corrected policy concerning the inclusion of mixed metal oxide products in the TSCA Inventory indicates that a Premanufacture Notice (PMN) will be needed for any mixed metal oxide product(s) that is currently in commerce, the final version of the revised policy should afford affected manufacturers or importers a sufficient period to comply with the new policy by submitting any required PMNs.

Utilizing such a procedure is a fair, appropriate, and orderly way to proceed as a matter of law and policy. Such a procedure also affords affected parties adequate notice of changes in EPA policy or construction before compliance is expected. As we have discussed, it would not be novel for EPA to use such a procedure to clarify TSCA Inventory requirements, because EPA has already done something similar several times before. The most recent example is EPA's 2010 clarification of the applicability of TSCA Inventory requirements to activated



phosphors.² We note that EPA's activated phosphors clarification was closely analogous to the relief we are seeking for mixed metal oxides, because it also involved a need to clarify the applicability of the 1995 Guidance on formulated and statutory mixtures to a particular group of products. EPA also issued a notice clarifying its policy concerning TSCA Inventory requirements for carbon nanotubes in 2008.³ Finally, EPA issued a correction of its TSCA Inventory policy for monomer acids and their derivatives in 2001.⁴ In each instance, EPA clarified or corrected a previously stated policy or position concerning inclusion of particular substances in the TSCA Inventory, and then afforded affected parties a reasonable period of time in which they could submit any PMNs or other notifications required to conform to the clarified or corrected policy.

We want to emphasize the need for a sufficient period for preparation and submission of any PMNs that may be needed for any mixed metal oxide product that does not conform to the TSCA Inventory policy that EPA ultimately adopts. In the case of activated phosphors, EPA afforded 18 months for this process after issuance of the final clarification. We think allowing the same compliance period following issuance of a final clarification for mixed metal oxides would be appropriate here. EPA also waived the limit of six chemicals per consolidation notice both for activated phosphors and for monomer acid. We request that EPA provide similar relief here.

Although we think it is clear that EPA policy is evolving with respect to products containing mixed metal oxides and that an orderly procedure for clarifying EPA policy and effectuating any clarification is needed, we also believe that the substance of EPA policy on mixed metal oxides is still uncertain. The members of the Statutory Mixtures Group would also be pleased to discuss with EPA the substance of its policy concerning mixed metal oxide products before EPA commences the clarification process.

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² EPA, Final Clarification for Chemical Identification Describing Activated Phosphors for TSCA Inventory Purposes, 75 Fed. Reg. 8266 (Feb. 24, 2010).

EPA, TSCA Inventory Status of Carbon Nanotubes, 73 Fed. Reg. 64946 (Oct. 31, 2008).

EPA, Correction to Chemical Nomenclature for Monomer Acid and Derivatives for TSCA Inventory Purposes, 66 Fed. Reg. 34193 (June 27, 2001).

⁵ 75 Fed. Reg. at 8270-71.

⁶ 75 Fed. Reg. at 8269; 66 Fed. Reg. at 34196.



Thank you again for considering the concerns of the Statutory Mixtures Group and its individual members. We look forward to constructive discussions that will culminate in an orderly process for clarifying and effectuating EPA policy concerning mixed metal oxides.

Sincerely,

Lynn L. Bergeson

Timothy D. Backstrom

Counsel, Statutory Mixtures Group

cc: Kevin W. McLean, Esquire (via e-mail)

Donald Sadowsky, Esquire (via e-mail)

Brian P. Grant, Esquire (via e-mail)

July 31, 2017

Via E-Mail

Jeffery Morris, Ph.D.
Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1300 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Uncertainty Concerning EPA Policy on Statutory Mixtures

Dear Jeff:

There has been a long history of uncertainty regarding the U.S. Environmental Protection Agency's (EPA) construction of a guidance document concerning formulated and statutory mixtures first issued by EPA in 1995. There have been numerous letters between individual submitters and EPA, or between industry groups and EPA, seeking clarification of EPA's interpretation and application of this Guidance. In many cases, EPA's responses have contributed confusion rather than providing clarity. Mixed metal oxides (MMO) are a category that industry has long assumed are statutory mixtures under the Guidance. EPA has consistently affirmed that the 1995 Guidance is still in effect, but there have been disparate interpretations of this document, up to and including the October 7, 2016, letter from Kevin McLean. In some cases, EPA has pursued enforcement action against companies that relied in good faith on this written Guidance.

MMOs are one category that appear to be included in the "statutory mixtures" that are described in Section III.B. of the Guidance document. In all cases in Section III.B., two or more substances react to form a complex product that, and despite the fact that a reaction has occurred, the Guidance indicates that the resulting product is considered to be a mixture in determining whether or not the resulting product must be listed in the TSCA Inventory. In some cases, the combinations are considered to be mixtures of the starting materials, while in other cases the combinations are considered to be mixtures of the individual products.

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EPA, Toxic Substances Control Act [(TSCA)] Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures (Guidance), available at https://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf.

² See Index -- TSCA Section 8(b)(2) Categories Listing Documents (Attachment).



Section III.B.2. in the Guidance states:

Certain combinations of metals, inorganic metal compounds and inert supports, which are frequently used for commercial purposes, including for use as solid phase heterogeneous catalysts, are also considered to be mixtures for the purposes of the TSCA Inventory.

Like other statutory mixtures, these combinations arise when a chemical reaction occurs in the formation of a product, but the combination is nevertheless considered a mixture.

Potential Interpretations

This language includes solid phase heterogeneous catalysts, but there is nothing in the language suggesting that it is limited to such catalysts. The category states simply that the combinations "are frequently used for commercial purposes, *including*" use as a heterogeneous catalyst. The language also does not limit the category to substances that have "inert supports"; rather, it specifies combinations of "metals, inorganic metal compounds and inert supports." There are a number of ways to interpret this sentence:

- 1. All three members of the list must be present. "Metals" and "inorganic metal compounds and inert supports." This construction would require that, to qualify as a statutory mixture, the mixture would have to be a combination of one or more metals, one or more inorganic metal compounds, and an inert support;
- 2. The list is comprised of two cases. "Metals" **or** "inorganic metal compounds **and** inert supports" would require that to qualify as a statutory mixture, the mixture would have to be a combination of only metals or a combination of only inorganic metal compounds and inert supports;
- 3. The list is comprised of two cases: "metals and inert supports" or "inorganic metal compounds and inert supports." That is, inert supports are a predicate to qualifying as a statutory mixture under Section III.B.2, but may be combined with either metals or inorganic metal compounds.
- 4. Any of the three members of the list may be present and no member of the list is required to be present. "Metals" or "inorganic metal compounds" or "inert supports" would require that to qualify as a statutory mixture, the mixture could be a combination of any of those substance types except for those that are specifically excluded by other portions of the Guidance

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(e.g., intermetallic compounds). In this case, inert supports are not a predicate to the applicability to this class of statutory mixtures.

The specific examples that follow the preamble to Section III.B.2. can be evaluated for consistency with each of these potential interpretations of the Guidance. This presumes that any interpretation of the literal language of the Guidance that cannot be reconciled with each of the specific examples provided by EPA must be incorrect. This type of analysis provides a logical methodology for selecting a reasonable construction of the Guidance, but such an analysis is not intended to preclude EPA from adopting a different or more restrictive policy concerning statutory mixtures after reasonable prior notice.

Example 8 of the Guidance relates to supported metal catalysts. The example includes a catalytic metal (Pt, Pd, Rh, or Ni) and three examples of common solid support materials (SiO₂, Al₂O₃, or C). The example explains that the "catalytic ingredient is dispersed in the internal porosity of such supports as silica gel, alumina or charcoals." It further explains that such catalyst/support combinations may be formed by reaction: "Pt/C was prepared by the reduction of PtCl₂ adsorbed on charcoal. Although a reaction was involved in the preparation, the resultant catalyst is represented in terms of the products formed and is viewed under TSCA as a mixture of the two substances, platinum and carbon." Here the Guidance is quite specific, describing a mixture of an active catalyst and an inert support. Neither the Guidance nor Example 8 limits the inert support to silica, alumina, and activated charcoal, although these are the most common inert supports. The inert support could be an organic polymer (such as polystyrene). Furthermore, there is no specific limitation that the active catalyst be a metal. Again, most supported catalysts are metals, but a reasonable reading of the Guidance and Example 8 allows an inorganic metal compound to be the active catalyst. In any case, it is clear that the final catalyst (as opposed to the starting material) and the inert support must both be listed on the Inventory. Looking back on the four potential interpretations of III.B.2., Example 8 is an example of a metal and an inert support. If the inert support is activated charcoal, there is no inorganic metal compound present. Example 8 is contrary to interpretation 1, in which a "metal" is combined with an "inorganic metal compound" and an "inert support." It also is contrary to interpretation 2, which would allow for combinations of metals (e.g., alloys) or a combination of inorganic metal compounds and inert supports. Example 8 is an example of a metal and an inert support. Therefore, Example 8 only can be reconciled with interpretations 3 and 4, in which different combinations of metals and inert supports or inorganic metal compounds and inert supports are formed.

Example 9 of the Guidance relates to zeolites. Zeolites are aluminosilicates that provide a wide range of functionality, but are most commonly used as adsorbents and catalysts. Example 9 states that "[z]eolites are considered for TSCA purposes to be mixtures of the substances used to manufacture them. The individual reactant materials used to produce zeolites are required to be listed separately on the Inventory. The application of EPA's guidance is not



affected by the chemical composition of the zeolite under consideration." It is noteworthy that in this example and unlike Example 8, it is the starting materials, rather than the final products, that must be listed on the TSCA Inventory. In fact, for zeolites, the final composition of the zeolite has no bearing on the application of the Guidance. Looking at the four potential interpretations of the preamble of Section III.B.2., Example 9 can only be reconciled with interpretation 4. Unlike the metal-supported catalysts in Example 8, zeolites are fairly homogenous structures. No part of a zeolite could be considered an "inert support," since the zeolite is primarily active at nearly any point on the surface. There is no inert location and there are no metals present. Zeolites are simply combinations of "inorganic metal compounds" without metals or inert supports being present.

Example 10 of the Guidance relates to MMOs. Example 10 considers "a cobalt oxide-aluminum oxide catalyst. A mixed hydroxide precipitate formed by the reaction of sodium hydroxide and an aqueous solution of cobalt (II) nitrate and aluminum nitrate is heated in air to produce a mixed oxide catalyst. Some of the cobalt is known to be oxidized to Co(III) in the process. In this case, cobalt (II) oxide, cobalt (III) oxide and aluminum oxide would each be reported for the Inventory. More complex compounds of cobalt and/or aluminum which may be formed incidentally in the manufacture of the catalyst mixture are not reported." As with the zeolites example, this example includes no metals (only inorganic metal compounds). An MMO may be a combination of inorganic metal compounds and an inert support or simply a combination of inorganic metal compounds. Like Example 9 and unlike Example 8, there is no specific mention in Example 10 of an inert support. An MMO that includes an inert support could be reconciled with interpretation 2, 3, or 4, but an MMO that does not include an inert support can only be reconciled with interpretation 4.

Thus, although a particular MMO may or may not include an inert support, the specific MMO described in Example 10 is only consistent with interpretation 4. Thus, both Example 9 and Example 10 are contrary to interpretations 1, 2, and 3, and only interpretation 4 can be considered to be consistent with all three examples.

Incidental Formation

EPA has in various letters written after the publication of the Guidance specifically noted the "formed incidentally" limitation in Example 10. The most reasonable construction of this language is that no more complex compound formed incidentally in the reaction between the various metal oxides needs to be separately listed in the Inventory, but each of the constituent metal oxides present in the MMO must be listed. Nothing in this language or elsewhere in the Guidance presumes that the MMO formed in the reaction described in Example 10 consists of discrete regions of cobalt(II) oxide, cobalt(III) oxide, and aluminum oxide. Nor is there a specific reason to believe that co-precipitating cobalt and aluminum hydroxide and heating the mixture in air would form such discrete regions. It is more likely that the mixed

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metal oxide product is a somewhat random, fairly homogenous material with the three metal species (cobalt(II), cobalt(III), and aluminum) interspersed among oxygen atoms at either random or regular intervals. The substance could be crystalline or amorphous -- neither Example 10 nor the III.B.2. preamble text specifies crystallinity (or lack thereof) as a predicate for the application of this Guidance. Moreover, unlike Examples 8 and 9, which specifically state whether the final products (Example 8) or the starting materials (Example 9) are what must be separately listed on the Inventory, Example 10 does not specify which case to use. The statement that "cobalt (II) oxide, cobalt (III) oxide and aluminum oxide would each be reported for the Inventory" specifies that rather than identifying any complex combination of the three metals and oxygen that may be formed at any point in the final combination, the manufacturer is permitted to describe the final combination as a mixture of the three metal oxides.

In summary, the text of paragraph III.B.2. of the Guidance and the three supporting examples lead to the conclusion that any combination of metals, inorganic metal compounds, and/or inert supports may be described as a statutory mixture. Furthermore, depending on the specific example, the combination may be described as either a mixture of the starting materials, as in Example 9, or a mixture of the final products, as in Examples 8 and 10. In addition, although all three examples include specific mention of catalysts or a class of substances that can be used as catalysts, nothing in the Guidance suggests that this class of statutory mixtures is limited to catalysts. The text of III.B.2. simply states that this class of statutory mixtures *includes* "solid phase heterogeneous catalysts." Finally, neither Example 9 nor Example 10 specifies that an inert support is a predicate for being considered a statutory mixture. Indeed, zeolites by their nature lack inert supports, and the MMO described in Example 10 does not include an inert support. Given the specific language in the section preamble and the three examples, only interpretation 4 accurately characterizes all the three examples.

MMOs Listed on the Inventory

The fact that numerous MMOs are listed on the TSCA Inventory does not contravene a broad construction of the Guidance. These MMOs were added to the Inventory as a result of premanufacture notices, but there are many reasons that manufacturers might submit notices to EPA for substances that are otherwise exempt from reporting. There are thousands of polymers listed on the Inventory that arguably qualify for the polymer exemption. There are also examples of UVCB substances that are actually simple mixtures of a small number of substances that manufacturers nevertheless describe as a UVCB substance for commercial expediency. The mere fact that a particular manufacturer has deemed it to be commercially expedient to seek a separate listing on the TSCA Inventory does not imply that the manufacturer was under any legal compulsion to do so.



Conclusion

EPA has confirmed that the 1995 guidance on formulated and statutory mixtures remains in effect. A careful analysis of the literal language of paragraph III.B.2. of the Guidance and of Examples 8, 9, and 10 supports the broad construction set forth in interpretation 4 above. If EPA wishes to adopt a different or more restrictive policy concerning listing of MMOs, the correct approach is not to undertake incremental enforcement against particular MMO manufacturers who have relied in good faith on a broad construction of the Guidance. Rather, EPA should clarify its preferred policy concerning listing of MMOs, utilizing a procedure that provides prior notice, an opportunity to comment, and an opportunity for all affected MMO manufacturers to submit any notices that may be needed to conform to the clarified policy. This is exactly the approach that EPA took with activated phosphors.

In reviewing this letter and the other correspondence regarding this matter, we ask that EPA employees place themselves in the shoes of affected entities and consider how these entities would reasonably interpret paragraph III.B.2. of the Guidance. Rather than straining for any interpretation that cannot be readily reconciled with the literal language of the Guidance, the fairest approach is for EPA to clarify its preferred policy and then afford affected entities a reasonable opportunity to comply with that policy.

Sincerely,

Lynn L. Bergeson

Attachment

Index -- TSCA Section 8(b)(2) Categories Listing Documents

- 1. August 4, 2006, Letter from G. McCarney, 3M, to K. Anapolle, OPPT Industrial Chemistry Branch, with questions regarding TSCA Section 8(b)(2) categories. Copy not available.
- 2. September 18, 2007, Letter from T. Williamson, Chief, OPPT Industrial Chemistry Branch, to G. McCarney, 3M, stating EPA did not intend for the Section 8(b)(2) categories to determine inventory status for any actual chemical substances.
- 3. November 26, 2007, Letter from M. Walls, ACC, to T. Williamson, OPPT, demonstrating the September 18, 2007, letter was inconsistent with TSCA and prior agency guidance and requesting its withdrawal.
- 4. May 28, 2008, Letter from T. Williamson, OPPT, to M. Walls, ACC, stating the Section 8(b)(2) category listings should not be used to cover chemically manufactured products for TSCA Inventory and reporting purposes.
- 5. August 29, 2008, Letter from M. Walls, ACC, to J. Gulliford, OPPT, requesting withdrawal of the May 28, 2008, letter and meeting.
- 6. October 8, 2008, Meeting of ACC representatives with R. Lee, Director, OPPT Economics, Exposure and Technology Division, and others in that Division.
- 7. November 12, 2008, Meeting of DuPont Microcircuit Materials representative with R. Lee, OPPT and members of his staff. Copy not available.
- 8. December 22, 2008, Letter from R. Lee, OPPT, to M. Walls, ACC, stated EPA was discussing the possibility of developing a clarification notice.
- 9. June 9, 2009, Letter from M. Walls, ACC, to R. Lee, OPPT, demonstrating that guidance for the 2006 TSCA IUR is consistent with historical industry understanding of the scope of the TSCA Section 8(b)(2) category listings.
- 10. July 21, 2009, Letter from R. Lee, OPPT, to M. Walls, ACC, acknowledging June 9, 2009, letter and stating EPA has formed a workgroup to clarify how EPA regards the Section 8(b)(2) categories, with publication of a draft notice expected in Fall 2009. Copy not available.

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- January 2010, EPA posts its December 2009 Action Initiation List, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."
- 12. Spring 2010 Regulatory Agenda, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."
- 13. Fall 2010 EPA Regulatory Plan and Semi-Annual Regulatory Agenda, RIN 2070-AJ68, "TSCA Inventory; Clarification for Chemical Identification Describing Statutory Mixtures, Including Ceramic Materials, Cements, and Frits for TSCA Inventory Purposes."
- 14. June 16, 2010, Letter from coalition of 13 trade associations and companies expressing concern regarding EPA's "apparent intent to delist" Section 8(b)(2) categories.
- 15. February 9, 2011, Meeting of ACC and OPPT to discuss TSCA categorical Inventory listings.
- 16. April 13, 2011, Letter from J. Prero, ACC, to L. Fraser, OGC, following up on February 9, 2011 meeting.
- 17. April 26, 2011, Meeting of ACC and member companies with OGC to discuss legal significance of TSCA categorical Inventory listings.
- 18. August 19, 2011, Letter from M. Walls, ACC, to W. Cleland-Hamnett and C. Kymn, OIRA, OMB, opposing EPA's plan to issue a clarification for chemical identification in RIN 2070-AJ68.
- 19. June 2012, Unified Regulatory Agenda does not include RIN 2070-AJ68.
- 20. March 4, 2016, Letter from L. Bergeson, B&C, to K. McLean, OGC, regarding requesting a meeting with OGC to discuss the legal implications of when EPA applies new nomenclature approaches.
- 21. April 6, 2016, Letter from L. Bergeson, B&C, to K. McLean, OGC, thanking McLean for March 30 meeting and requesting clarification.
- 22. October 7, 2016, Letter from K. Mclean, OGC, to L. Bergeson, B&C, referring to letters and meeting and regarding Example 10 in 1995 EPA guidance document *Products Containing Two or More Substances: Formulated and Statutory Mixtures*.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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DEC 27 2017

BERGESON & CAMPBELL, P.C.

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Lynn L. Bergeson, Esq. Bergeson & Campbell PC 2200 Pennsylvania Avenue, NW, Suite 100W Washington, DC 20037-1701

Dear Ms. Bergeson,

I am writing in response to your letter emailed to me on July 31, 2017 regarding statutory mixtures. In this letter, you discuss your interpretations of certain parts of the EPA's 1995 guidance document "Toxic Substances Control Act Inventory Representation For Products Containing Two Or More Substances: Formulated and Statutory Mixtures" (the "guidance on mixtures"). You state that there is uncertainty regarding this document, and you express your preferred interpretation of this guidance on mixtures with respect to mixed metal oxides (MMOs) and statutory mixtures.

Your letter treats MMOs as combinations of chemical substances. However, in the Agency's guidance on mixtures, an MMO is actually a single chemical substance that is the chemical product of the reaction occurring between the reactants used to manufacture the MMO. The different metals of an MMO are chemically interconnected through bonding to the oxygens into a distinct molecular or lattice structure. The degree of specificity in the chemical identification of a given MMO depends on the level of knowledge about its chemical composition and structure. Because each distinct MMO is a chemical substance representing a particular chemical composition as actually manufactured, any MMO that is not already specifically listed on the Inventory is subject to PMN reporting where not exempt.

Many MMO listings on the TSCA Inventory are consistent with the guidance on mixtures. Additionally, Example 8 (about "Rutile, neodymium") in the 1995 guidance document "TSCA Substances Control Act Inventory Representation For Chemical substances Of Unknown Or Variable Composition, Complex Reaction Products And Biological Materials: UVCB Substances" further illustrates that an MMO is a single chemical substance.

The basis of your statements on MMOs and statutory mixtures appears to be the guidance on mixtures. Your letter states that MMOs are one category that appears to be included in Section III.B on statutory mixtures. However, MMOs are not actually mentioned or described in the guidance. Your letter also suggests that both parts 1 and 2 of Section III.B describe a number of examples of statutory mixtures. The various examples in parts 1 and 2 in fact describe several types of mixtures: statutory mixtures, formulated mixtures, and chemically manufactured mixtures. We recognize that the heading of Section III.B - "Combinations that are considered to be statutory mixtures under TSCA" — is unfortunate since it could be interpreted that all of the examples discussed in parts 1 and 2 are statutory mixtures. However, the Agency has provided consistent interpretation of the guidance on mixtures to explicate the various parts.

Part 2 and its Examples 8, 9, and 10, for example, discuss other kinds of mixtures that are not statutory mixtures. Regarding Example 10, your letter references this example for the purposes of illustrating an MMO. As mentioned, the guidance on mixtures does not mention or describe MMOs. Example 10 describes a scenario intended to produce individual metal oxides, and the mention of any more complex materials, which may or may not be MMOs, refers to incidentally formed substances that would only have exempt commercial purposes. Your letter further appears to interpret the existence of examples in Section III.B very broadly suggesting that the scenarios presented could be considered representative of a variety of situations. The letter suggests that these examples would not have to be limited to the particular types of chemicals (metals, inorganic metal compounds, and/or inert supports) described in each one, and as a result, each example could be inferred to be about an MMO. On the contrary, the examples in Section III.B were meant to describe specific chemical manufacturing scenarios of the chemicals described in each one. Consequently, these examples are limited to just what they describe, and none of them describes MMOs. For these reasons, the EPA disagrees with your conclusion that Examples 8, 9, and 10 in Part 2 are illustrative of MMOs and therefore support the interpretation that MMOs are statutory mixtures.

Your letter also asserts that the fact that numerous MMOs are listed on the Inventory, allegedly as a result of premanufacture notification (PMN) reporting, does not contravene your interpretation of the guidance on mixtures. This premise is incorrect as there are many MMOs listed on the Inventory, mostly from initial Inventory reporting. Your letter further asserts that the existing MMO listings that did result from PMN reporting do not imply that the manufacturers were under any legal compulsion to report those substances as MMOs, suggesting instead that these manufacturers would have been permitted alternative ways of identifying these substances, e.g., as mixtures (your letter bases this assertion on an analogy to optionally filing a PMN instead of using the Polymer Exemption, an analogy that does not apply). The EPA also disagrees with this assertion because, although a company does have a choice as to whether to take advantage of an available exemption under TSCA section 5, a company does not have a choice to have an Inventory listing for something that does not constitute a (new) chemical substance.

As a final note, your letter states that the EPA should clarify its preferred policy concerning the listing of MMOs using a Federal Register notice and comment approach similar to the one taken with activated phosphors. The type of clarification and process you suggest would appear to be similar to a process our Office worked on during the 2008-2012 timeframe in order to clarify policy on MMOs and statutory mixtures and affirm the positions we have communicated through various meetings and letters over many years. Our communications on this have been consistent and extend back to at least the year 2000. Lastly, we are open to suggestions as to areas of uncertainty and ways they might be clarified.

Should you have further questions or suggestions, please feel free to contact me at (202) 564-3810.

Sincerely,

Jeffery T. Morris, Ph.D.

Director

Office of Pollution Prevention and Toxics

Jamy Holy Mattle

From: Lynn L. Bergeson [lbergeson@lawbc.com]

Sent: 10/18/2018 11:57:05 AM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: Our Summary

Ex. 5 Deliberative Process (DP)

The U.S. Environmental Protection Agency (EPA) issued on October 16, 2018, a proposed rule that would establish significant new use rules (SNUR) under the Toxic Substances Control Act (TSCA) for 13 chemical substances that are the subject of premanufacture notices (PMN). 83 Fed. Reg. 52179. The proposed rule is significant. Unlike other recent SNURs (i.e., those acted on since entry into force of amended TSCA), the 13 chemical substances are **not** also subject to consent orders. For this reason, the preamble contains novel language to address the new circumstances and legal issues encountered in the proposed rule. The proposed SNURs would require persons who intend to manufacture (defined by statute to include import) or process any of the 13 chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity. The required notification will initiate EPA's evaluation of the intended use within the applicable review period. Persons may not commence the manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination. Comments on the proposed SNURs are due **November 2018**.

The proposed rule states that under TSCA Section 5(a)(2), EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance;
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance;
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance; and
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

For each of the 13 chemical substances, the proposed rule provides the following information:

- PMN number;
- Chemical name (generic name, if the specific name is claimed as confidential business information (CBI);
- Chemical Abstracts Service (CAS) Registry Number (RN) (if assigned for non-confidential chemical identities);
- · Basis for the SNUR; and
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the
 chemical substances if a manufacturer or processor is considering submitting a significant new use notice (SNUN)
 for a significant new use designated by the SNUR.

EPA states that this information may include testing not required to be conducted but that would help characterize the potential health and/or environmental effects of the PMN substance. According to the proposed rule, any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, and other available information on appropriate testing for the chemical substance. Further, the proposed rule states that any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA

also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA "encourages all SNUN submitters to contact EPA to discuss any potential future testing."

Commentary

All previous SNURs proposed or promulgated for PMNs being considered under new TSCA were cases where EPA had negotiated orders under Section 5(e) and thus were so-called "5(e) SNURs." Based on our experience, there are many PMN chemicals for which some regulatory requirement may be needed to meet the provisions of amended TSCA, but we do not believe that a Section 5(e) order is needed in all such cases. The proposed SNUR is interesting, important, and controversial, as this is the first time under the new law for which EPA is proposing to apply SNUR authority to non-5(e) order PMN cases.

In the proposed rule, EPA has emphasized that all of the subject PMN chemicals were "undergoing PMN review" when the proposed rule was signed (October 5, 2018). The proposed rule explains that this means that none of the chemicals was presently in commerce, as a Notice of Commencement (NOC) of manufacture or import had not been received and the chemicals have not been added to the TSCA Inventory. Thus, EPA concludes the proposed significant new uses are not ongoing.

EPA also took the novel step in the proposed rule of designating a given date (October 10, 2018) in the preamble as the cutoff date for determining whether the new use is ongoing. EPA states that the objective of its approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule. EPA also states that, following promulgation of the final SNUR, any such significant new use would have to cease upon the effective date of the final rule and be subject to advance notification requirements in the form of a SNUN. Under new TSCA, such notifications require EPA review, Section 5(a)(3) determinations, and regulatory action as needed.

Although not discussed in the preamble we have learned that since signature, EPA has made "not likely" Section 5(a)(3)(C) determinations for the 13 new chemicals included in the proposed rule. Thus, it appears that EPA believes it has sufficient information to make this determination under the conditions of use.

EPA is likely to receive many comments on this proposed SNUR from diverse stakeholders. We will hold off on offering any reactions until we have had the chance to think through the issues more carefully. We, nonetheless, commend EPA for taking this step and initiating consideration and debate on the approach it is proposing in the rule as a way to deal with these types of PMN chemicals and the issues presented by them. As we noted at the outset of this commentary, the rule is interesting, important, and controversial, and this will remain the case as we, other stakeholders, and EPA go forward in the rulemaking process which, after promulgation by EPA of the final rule, may invite one or more legal challenges to the approach taken.

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]

Sent: 6/25/2018 4:48:52 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: 11 AM ET webinar

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, June 25, 2018 12:28 PM

To: Lynn L. Bergeson

Subject: RE: 11 AM ET webinar

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Ex. 6 Personal Phone

beck.nancy@epa.gov

From: Lynn L. Bergeson [mailto:lbergeson@lawbc.com]

Sent: Monday, June 25, 2018 10:44 AM

To: 'Kramer, Claire' <ckramer@bloombergnext.com>; michael.gould@rahn-group.com; mbogle@vertellus.com; Beck,

Nancy <Beck.Nancy@epa.gov>

Cc: Heidi Brown Lewis <hlewis@lawbc.com>

Subject: RE: 11 AM ET webinar

Will do -logging in now

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From: Kramer, Claire [mailto:ckramer@bloombergnext.com]

Sent: Monday, June 25, 2018 10:40 AM

To: michael.gould@rahn-group.com; mbogle@vertellus.com; beck.nancy@epa.gov; Lynn L. Bergeson

Cc: Heidi Brown Lewis **Subject:** 11 AM ET webinar

Good Morning Everyone,

I look forward to working with you on today's webinar. Please let me know if you have any questions as you are dialing in and logging in.

Thank you! Claire

Claire Kramer

Continuing Education/LMS Assistant

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]

Sent: 6/25/2018 2:21:05 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: webinar Attachments: 00245239.PPTX

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To: Lynn L. Bergeson; Heidi Brown Lewis

Subject: FW: webinar

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TSCA at 2: An Update on Implementation and Hot Topics

June 25, 2018

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Program

Opening -- Lynn L. Bergeson Managing Partner Bergeson & Campbell, P.C.

Agency Update -- Nancy B. Beck, Ph.D., DABT® Deputy Assistant Administrator Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency

Key Section 5 Concerns -- **Misty L. Bogle** Global Product Stewardship Manager Vertellus

Key Section 5 Concerns -- Michael Gould EH&S Committee Chairman RadTech North America

Questions

Close

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Nancy B. Beck, Ph.D., DABT®

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

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EPA Office of Chemical Safety & Pollution Prevention (OCSPP) Accomplishments and Priorities under TSCA

Nancy B. Beck, PhD, DABT
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
June 25, 2018

beck.nancy@epa.gov



Toxic Substances Control Act (TSCA) Year 2 Accomplishments

- Addressing Persistent, Bioaccumulative, and Toxic (PBT) Chemicals
- Dust-Lead Hazard Standards
- Final Mercury Reporting Rule
- Transparency and Confidential Business Information (CBI)
 - Unique Identifier
 - · Generic Name Guidance
 - Expanded Access to CBI Guidance
- Alternative Strategy to Reduce Animal Testing





TSCA Year 2 Accomplishments

- · New Chemicals Points to Consider
- Ten Problem Formulations
- Asbestos Significant New Use Rule (SNUR)
- Systematic Review Approach
- Proposed Fees Rule



Near-Term Priorities

- Methylene Chloride Final Rule
- Establishing a Fee Program
- Updating TSCA Chemical Substance Inventory
 - · CBI Review Plan Rule
- Completing First Ten Chemicals Risk Evaluations
- Selecting the Next 40 Chemicals for Prioritization
- Addressing PBTs
- Refining New Chemicals Review





Misty L. Bogle Global Product Stewardship Manager Vertellus

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Conditions of Use (COU)

- Section 3 Definition: "... the circumstances, as determined by [EPA], under which a chemical is intended, known, or reasonably foreseen to be manufactured, processed..."
- The Office of Pollution Prevention and Toxics (OPPT) considered COU in the past, including foreseeable COU, and would impose restrictions (e.g., use limitations, water release limitations) to protect against those foreseen COU

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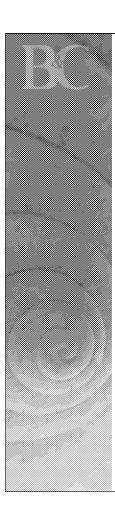
:0



Key Concerns

- If the U.S. Environmental Protection Agency (EPA) identifies a COU in which hazard is not low for health and for ecotoxicity ("low/low" cases), EPA is proposing regulation in nearly all cases
 - > Basis: "somebody might" exceed the level of concern
 - > Any conceivable vs. reasonably foreseeable

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Key Concerns

- If EPA determines it is required to regulate under Section 5(f) or Section 5(e), it must do so "to the extent necessary" to protect against unreasonable risk
 - > What is "the extent necessary"?
- Example for consideration:
 - An employer requires workers to wear gloves and gloves are provided to all workers
 - If EPA believes that a worker may choose not to wear the required gloves, is that a foreseeable COU and reasonable basis for a SNUR? Does adding a TSCA regulation in addition to the existing Occupational Safety and Health Administration (OSHA) regulation meet the "extent necessary" provision?

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Key Concerns

- Notable outcomes
 - EPA requiring workplace protection duplicative to OSHA requirements
 - Very difficult to "test out" of restrictions -- absent testing to demonstrate low hazard, EPA imposes regulation

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Case Study

BACKGROUND

- Stereoisomer -- non-specific analog already on TSCA Inventory
- Ester -- no releases to water, worker protections included
- Low Volume Exemption (LVE) granted -- no unreasonable risk
- Premanufacture Notification (PMN) application in June 2017
- Added aquatic test data
- Same controls in place
- PMN conditions "not likely to present unreasonable risk"
- Concern about changes to COU -> non-5(e) SNUR

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Questions for EPA

- Will we see additional guidance on the Agency's interpretation of "reasonably foreseen" circumstances in new chemical review?
- Can industry expect to be regulated in every case, unless our substance is completely nonhazardous?
- When will the backlog of non-5(e) SNURs be resolved?
- Feedback on issues of concern related to COU
- Could/should EPA revisit the option to consider relative risk?
 - Because EPA no longer considers relative risk in new chemical review, less hazardous new chemicals are more highly regulated than more hazardous existing chemicals

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Michael Gould EH&S Committee Chairman RadTech North America

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Business Concerns with SNURs

- Consent order or non-order SNUR trigger
 - Section 12(b) export notification if substance present at >1 percent
 - > Supply chain communication to all recipients
 - Recordkeeping requirements apply to all levels of supply chain
 - Lower reporting thresholds for Chemical Data Reporting (CDR)
- Some companies prohibit purchasing a substance with a SNUR due to a perception of enhanced risk

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Current Forecast on SNURS

- Many more SNURs in our future
 - > Recent analysis shows:
 - About 5 percent of initial determinations are not likely
 - 11.5 percent of final determinations are not likely
 - Is this trend reversible?
- Necessity of SNURs
 - > Role of workplace standards
 - > Is EPA coordinating with OSHA?

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Case Study

BACKGROUND

- Pre-amended TSCA, PMN filed for substance regulated under LVE
 - Substance is low molecular weight polymer of a discreet chemical substance with known toxicity concerns
- PMN initially dropped, but pulled back into re-evaluation after amended TSCA passed

CURRENT STATUS

- Conclusion of re-evaluation under amended TSCA included certain restrictions
 - Including concentration limitation for imported products
 - Concentration limitation makes it impossible for manufacturer to import raw material
- Re-evaluation also focuses on toxicity of parent compounds versus final product

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Question for EPA

- Does EPA evaluation take into account the fact that by making the discreet substance into a polymer, the substance has less exposure potential?
 - > Less accessible at the cellular level
 - More secure in final cured articles

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Related SNUR Issues

- Significant delays, especially in SNUR publication
 - Order SNURs no reason to delay; required by statute, restrictions established in consent order
 - Non-order SNURs -- authority has been questioned
- Section 5(e) SNURs must be prompt
- Fish or cut bait on non-order SNURs
- Creative solutions when hazards can be addressed by limiting how substance is manufactured
 - Proposal to create new Inventory flag for chemicals with workplace exposure concerns
- Example for consideration: The EPA conservative model predicts exposure a level order of magnitude below a chemical's concentration of concern (COC)
 - Is it foreseeable that COC could be exceeded?
 - Is this a reasonable basis for a SNUR?

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Questions



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Thank You

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Message

From: Lynn L. Bergeson [lbergeson@lawbc.com]

Sent: 6/25/2018 1:46:48 PM

To: Beck, Nancy [Beck.Nancy@epa.gov]

Subject: RE: webinar

Thanks

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, June 25, 2018 9:45 AM

To: Lynn L. Bergeson **Subject:** RE: webinar

Ex. 5 Deliberative Process (DP)

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Monday, June 25, 2018 9:30 AM

To: Lynn L. Bergeson **Subject:** RE: webinar

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Talk to you soon, Nancy

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Sent: Monday, June 25, 2018 9:11 AM **To:** Beck, Nancy Beck.Nancy@epa.gov>

Subject: RE: webinar

Morning Nancy,

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Thanks

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From: Lynn L. Bergeson

Sent: Friday, June 22, 2018 7:13 PM

To: 'Beck, Nancy' **Subject:** webinar

Nancy,

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, June 22, 2018 7:04 PM

To: Lynn L. Bergeson **Subject:** RE: webinar

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From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]

Sent: Friday, June 22, 2018 4:00 PM

To: Lynn L. Bergeson **Subject:** RE: webinar

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From: Lynn L. Bergeson [mailto:lbergeson@lawbc.com]

Sent: Friday, June 22, 2018 3:55 PM **To:** Beck, Nancy Beck.Nancy@epa.gov>

Subject: RE: webinar

Hi Nancy,

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Sent: Friday, June 22, 2018 3:51 PM

To: Lynn L. Bergeson **Subject:** webinar

Lynn,

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Thanks! Nancy

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